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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵:

G06F 15/42

(11) International Publication Number: WO 94/27238

(43) International Publication Date: 24 November 1994 (24.11.94)

CA

US

(21) International Application Number:

PCT/CA94/00216

(22) International Filing Date:

19 April 1994 (19.04.94)

(30) Priority Data:

2,096,292 143,517 14 May 1993 (14.05.93)

29 October 1993 (29.10.93)

(60) Parent Application or Grant (63) Related by Continuation

US

143,517 (CON)

Filed on

29 October 1993 (29.10.93)

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(81) Designated States: AT, AU, BB, BG, BR, BY, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KG, KP, KR, KZ, LK, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ELECTRONIC WORKSHEET SYSTEM FOR MICROBIOLOGY TESTING AND REPORTING

(57) Abstract

A system for testing microbiological specimens and reporting the results thereof. The system comprises at least one workstation which is coupled to a patient information database and a microbiology database. The workstation has data entry means which include a scanner. The specimen is assigned a machine readable identifier. The machine readable identifier is also referenced to data in the patient information database. The workstation uses the scanner to read the identifier assigned to the specimen and retrieve patient information for the specimen. The workstation produces a screen display which comprises the retrieved patient information in addition to interactive fields for performing the microbiological testing of the specimen. The interactive fields include a field for inserting the type of medium used, a field for inserting the observation concerning the specimen, and a field for inserting a description relating to the specimen. Once the testing and recording of results have been completed, the workstation produces a report in electronic form that can be transmitted to a remote location.

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Title:

ELECTRONIC WORKSHEET SYSTEM FOR MICROBIOLOGY TESTING AND REPORTING

5 FIELD OF THE INVENTION

This invention relates to an electronic worksheet system for use in a microbiology specimen testing laboratory. More particularly, the present invention relates to a system for testing, recording and generating test results and reports for microbiological specimens.

BACKGROUND OF THE INVENTION

The testing of microbiological specimens is an important aspect of modern health care. Through the testing and analysis of microbiological specimens taken from a patient, health care workers are able to diagnose and treat a wide variety of ailments which can afflict people.

While modern microbiological specimen testing is invaluable to the practice of medicine, it relies heavily on manual procedures and input from highly skilled microbiologists for most stages in the procedure. Because of the labour intensive nature of current microbiological testing procedures, costs continue to rise with little or no significant improvements in specimen throughput.

Thus, there is a need to provide a system for use in a microbiological testing facility which is capable of producing accurate testing and reporting in a cost effective manner.

BRIEF SUMMARY OF THE INVENTION

The present invention provides in the method of microbiological testing and reporting of a patient specimen in a medium, said specimen having a machine readable identifier, the improvement comprising: providing, in a database, patient

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information associated with said identifier, said patient information including patient identification information and patient age and patient sex identification information, and then selecting said specimen, reading said identifier, and displaying on a screen information including said patient identification information and said patient age and sex identification information, an identification of the type of said specimen, a medium box for insertion therein by a user of the type of medium used, and an observation box for insertion therein by a user of an observation concerning said specimen.

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BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made to the accompanying drawings, which by way of example, show preferred embodiments of the present invention, in which:

Figure 1 is a schematic view of a system according to the present invention;

Figure 2 is a logical flow diagram showing the steps 20 involved in collecting and testing a microbiological specimen according to the system of Figure 1;

Figure 3 is a diagrammatic representation of the Menu screen for the system of Figure 1;

Figure 4 is a diagrammatic representation of an electronic 25 microbiology worksheet screen which is generated by the system of Figure 1;

Figure 5 is a logical flow diagram showing in more detail the steps involved in generating an electronic microbiology worksheet according to the system of Figure 1;

Figures 6(a) to 6(e) are diagrammatic representations of Specimen Specific Test Windows for the electronic microbiology worksheet in Figure 4;

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Figures 7(a) is a diagrammatic representation of an Observations Window and the Patient Demographic and Specimen Data Window for the electronic microbiology worksheet of Figure 4;

Figures 7(b) to 7(j) illustrate list-boxes for the Observations Window of Figure 7(a);

Figure 8 is a logical flow diagram showing in more detail the steps involved in performing and recording the microbiological tests according to steps 258 and 259 in Figure 5;

Figure 9 is a logical flow diagram showing in more detail 10 the steps involved in sub-dividing a specimen to produce additional microbiological cultures according to the system of Figure 1;

Figure 10 is a diagrammatic representation of a Results Release Screen for the system of Figure 1;

Figures 11(a) to 11(g) are diagrammatic representations of various Test Library Windows for the Observation Window of Figure 7(a);

Figure 12 is a diagrammatic representation of a Pending Reports Screen for the system of Figure 1;

Figure 13(a) is a diagrammatic representation of the Bind 20 Bar-code Screen for the system of Figure 1;

Figure 13(b) illustrates the relationship between the plate bar-codes and the bar-code identifier for the patient;

Figure 14 is a diagrammatic representation of the Free Text Screen for the system of Figure 1;

25 Figure 15 is a diagrammatic representation of the Recorded and Free Text Screen for the system of Figure 1;

Figure 16 is a diagrammatic representation of the Review Screen for the system of Figure 1;

Figure 17 is a diagrammatic representation of the Slot 30 Status Screen for the system of Figure 1;

Figure 18 is a diagrammatic representation of the Sub-Culture Screen for the system of Figure 1;

Figure 19 is a diagrammatic representation of the Archive Screen for the system of Figure 1;

Figure 20 is a diagrammatic representation of the User Authorization Screen for the system of Figure 1;

Figure 21 is a diagrammatic representation of the Specimen Delete Screen for the system of Figure 1; and

Figure 22 is a diagrammatic representation of the Communication Screen for the system of Figure 1.

10 DETAILED DESCRIPTION OF THE PRESENT INVENTION

Reference is first made to Figure 1 which shows in schematic form an electronic worksheet system (indicated generally by reference 1) for use in a microbiology testing facility. The electronic worksheet system 1 comprises a number of workstations 10, which are 15 situated on workbenches in the microbiology testing facility. In the preferred embodiment, each workstation 10 comprises an IBM (trade mark) compatible personal computer 11, a colour monitor 12, a keyboard 14, a mouse 16, and a bar-code scanner 18. The computer 11 includes memory 13 for storing and running a system program 15. The 20 system program can be considered as comprising a software component (e.g. operating system) for running the workstation 10 and another software component (e.g. application program) for the electronic worksheet system 1. In the preferred embodiment, the software component for the electronic worksheet system 1 is written 25 in the Visual Basic Programming Language which can be run as a Windows (trade mark) application program manufactured by Microsoft, and also uses the Raima Datamanager manufactured by Raima Corporation of Issaquah, Washington. It will be appreciated by those skilled in the art that the software component of the electronic 30 worksheet system 1 can be implemented in another "windows" type programming language, for example, Hypercard (trade mark) for the Macintosh computer.

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Each workstation 10 also includes a network card 20 which is used to link the workstations 10 (computers 11) into a Local Area Network (LAN) indicated generally by reference 13. The size of the Local Area Network 13 (i.e. number of workstations 10) will depend on the size of the microbiology testing facility and the network 13 can be expanded as required. The Local Area Network 13 includes a file server 21, which comprises a computer (not shown) and disk storage for storing a microbiology database 28. The file server 21 gives the workstations 10 with access to the microbiology database 28.

The system 1 also includes a console workstation 24. The console workstation 24 serves as a "gateway" to another computer 22. In most cases, the microbiological testing laboratory is at a location which is remote from the place where the specimen is collected from the patient, e.g. a physician's office. Therefore, the system 1 according 15 to the present invention includes the console workstation 24 which provides a communication interface between the network 13 and the computer 22. The console workstation 24 controls the transfer of information between the electronic worksheet system 1 and the computer 22. It will be appreciated that the file server 21 and the console workstation 24 can be combined on a single computer which can run the software program for the electronic worksheet system 1 and also the gateway program 13, in the background for example. The computer 22 can be a personal computer, minicomputer or even a mainframe computer.

In the context of the present invention, the principle function of the computer 22 is to run the software for the Laboratory Information System 26. The Laboratory Information System 26 is an application program which is used to generate a computer data file for a patient who will be giving a specimen for microbiological testing. The patient data file is stored in computer memory and can be downloaded as an electronic file to the electronic worksheet system 1. In the preferred embodiment, the Laboratory Information System 26

produces a patient and specimen computer data file which includes patient demographic information and specimen data. The computer data file is assigned an accession number which provides an identifier for accessing the file and for linking the patient data file to the physical 5 microbiological specimen taken from the patient (see below). The accession number is also used by the electronic worksheet system 1 for the microbiological testing process as will be explained below. The Information System 26 can also be used for processing and storing the results of the microbiology testing.

In the following explanation, the system 1 according to the present invention is presented in the context of a microbiology testing laboratory. It will be appreciated however that the system 1 is suitable for other applications which involve a number of decision and processing steps. A feature of the system 1 is the ability to track the 15 testing (or processing) of an original specimen (or sample) and any number of subsidiary specimens (or samples) which are derived from the original specimen and/or subsequent tests.

Typically, the microbiological specimens are taken from a patient at a location (point of collection), e.g. doctor's office or medical 20 clinic, which is remote from the microbiological testing laboratory (and system 1). At the point of collection, patient information and specimen data for the patient are entered into the Laboratory Information System 26 to generate the patient and specimen computer data file, and the specimen is taken from the patient and linked to 25 computer data file by an accession number. The patient and specimen data file will generally include the patient's name, sex, date of birth, the specimen type, date of collection, point of collection, tests requested by the patient's physician, etc... The Laboratory Information System 26 stores the patient and specimen data file in the memory of 30 the computer 22 and uses the accession number for accessing the data file. The Laboratory Information System 26 also generates a specimen label for each specimen taken from the patient and the label is affixed to the specimen container. The specimen label includes the accession number in human readable and machine readable form (e.g. as a bar code) and other information from the patient and specimen data file, e.g. the patient's name and sex.

As will be explained below, the accession number is used in a number of ways. First, the accession number is used to track the specimen from the point of collection to the microbiological testing facility. Secondly, the accession number is used to identify the specimen during the testing procedure in the microbiological testing facility. Thirdly, the accession number is used to download the patient and specimen data file from the Laboratory Information System 26 to the electronic microbiological worksheet system 1.

Once the specimens have been collected from the patient, they are shipped or transported to the microbiological testing facility. The shipping of the specimens can be monitored by scanning the barcoded accession number on the specimen label and producing a waybill. At the microbiological testing facility, each specimen label is scanned and the appropriate number of test labels are then generated, which are used to label the test containers for the specimen. The type 20 of testing to be done on the specimen determines the number of test labels. (The specimen label generated by the Laboratory Information System 26 will include a test code which indicates the testing to be done on the specimen.) The type of testing also determines the medium which will be used for testing the specimen, e.g. a petri 25 plate(s), test tube, or a slide(s). This information can be conveniently saved in the patient and specimen data file and retrieved by scanning the bar-coded accession number on the specimen label when the specimen arrives at the testing facility.

For example, if the specimen is a stool sample, then scanning the specimen label will typically generate five test labels which can be used for the following known types of petri plates: a selinite broth plate, a Hekteon agar plate, a macConkey plate, a

sorbitol-macConkey plate, and a Campy agar plate. A test label is affixed to each of the plates and a portion of the sample is placed on each plate. Once the specimen plates have been prepared, they are distributed to the respective test areas (e.g. workbenches) in the laboratory. Most microbiological specimens require an incubation period before testing for pathogens can occur. The incubation is conducted according to the practice of the particular laboratory.

At some point prior to the bench testing of the specimen plates, the patient and specimen data file (which is stored in the 10 Laboratory Information System) is downloaded to the worksheet system 1 via the console workstation 24. (As will be explained in detail below, the worksheet system 1 uses the patient and specimen data to generate "an electronic microbiology worksheet"). The Laboratory Information System 26 can include a communications driver (not shown) which interfaces to the console workstation 24 or the communications interface (not shown) can run on the computer 22 system software (indicated generally by reference 27). If the computer 22 is located at a site remote from the system 1, then appropriate communications equipment would be needed. For example, the 20 communications equipment can comprise a communications modem 30 for transferring data to and from the (remote) computer 22 over conventional telephone lines 32 as shown. Since the microbiology testing facility is usually separate from the specimen collection facility, the computer 22 will be referred to a remote computer 22.

A feature of the system 1 is that the patient and specimen data file can be retrieved on each workstation 10 by scanning the barcoded accession number on the test label attached to the container (e.g. petri plate) or by using the keyboard to input the accession number. The system 1 uses this capability to construct the electronic microbiology worksheet as will be discussed below. Another feature of the system 1 is the capability to provide a standardized approach for the testing of each microbiological specimen. The system 1 includes

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built-in logic which produces pre-defined rules and steps for the particular testing of a microbiological specimen.

Reference is next made to Figure 2 which shows in flow chart form the steps involved in obtaining a microbiological specimen from a patient and testing the microbiological specimen using the electronic worksheet system 1 according to the present invention.

In most cases, the microbiological testing facility is separate from the specimen collection location (e.g the doctor's office or a medical clinic). At the specimen collection location (e.g. the doctor's office), the first step involves inputting information about the patient and the specimen into the Laboratory Information System 26 as indicated by block 202. The patient information includes patient's name, date of birth, sex, physician's name, etc., while the specimen information includes type of specimen, date of collection, type of tests 15 requested by the patient's physician, etc. The Laboratory Information System 26 uses the patient and specimen information to generate the patient and specimen computer data file and to produce a specimen label which is attached to the specimen collection container (block 204). As discussed above, the patient and specimen computer data file is linked to the specimen collection container by an identification code, i.e. the accession number. The accession number provides a unique code for identifying the specimen. The accession number is printed on the specimen label (which is affixed to the specimen collection container). The accession number appears both in human 25 readable and machine readable form. In the following description, the accession number (i.e. identification code) in machine readable form comprises a bar code, which can be easily printed and scanned using known technology. It will be appreciated that instead of a bar-code, any other suitable machine readable identifier could be used, for example an electronic chip with an embedded code, or a code encoded in a magnetic strip, which are attached to the specimen container. The

specimen container label also includes the patient name and accession number in human readable form.

Once the specimen collection container has been prepared, the microbiological specimen is taken from the patient and 5 placed inside the labelled specimen container as indicated in block 206. The specimen container is then shipped to the microbiological testing laboratory in block 208. As discussed above, the bar-coded accession number can be scanned to produce a waybill. A software program for this function can be implemented as part of the Laboratory Information System 26. At the microbiology testing facility, the specimen label is scanned and the required number of specimen test labels are generated (block 210). The number of specimen test labels is determined by the type of specimen and the type tests requested by the physician. The next step involves preparing the required medium (e.g. 15 petri plates, tubes or slides) for testing the microbiological specimen and attaching the specimen test labels to the plates, tubes or slides (blocks 212 and 214), and placing part of the specimen on each plate, tube or slide. If necessary, the plates, tubes or slides can be placed in an incubator for a predetermined time (block 215). Once the specimen has 20 undergone the required incubation (block 215), the specimen is ready for microbiological testing and is distributed to the microbiology stations for a microbiologist, a microbiology technologist or a technician to conduct testing according to the electronic worksheet system 1.

Before microbiological testing of the specimen can start, the technician must log-on to the system 1 (block 218) and download the patient and specimen computer data file from the Laboratory Information System 26 (block 220). Since most microbiological specimens undergo an incubation period (in order to cultivate the 30 pathogens), the patient and specimen computer data file can be downloaded during the incubation period 215. As will be discussed in detail below, the system 1 uses the patient and specimen data to

generate an electronic microbiology worksheet for conducting the microbiological testing and producing a test report which is communicated to the patient's physician.

The microbiological testing is commenced by using the 5 bar-code scanner 18 to scan or read the accession number on the specimen test label in block 222. As discussed above, the accession number provides a unique identifier for the specimen. The system 1 uses the accession number to link the specimen to the patient and specimen computer data file and generate an electronic 10 microbiological worksheet for the specimen (block 224). The electronic microbiological worksheet is then used by the technician to perform and record the microbiological testing for the specimen (block 226).

The following explanation will now consider in detail the electronic microbiology worksheet which is produced by the 15 system 1 for performing and recording the microbiological testing of a specimen (i.e. blocks 224 and 226 in Figure 2). The system 1 comprises an expert system which provides a systematic method for testing the specimen(s) and recording the microbiological test results, which are referred to as observations in the following discussion. Once the testing is completed, the system 1 generates an electronic test result/report file which summarizes the observations from the microbiological testing. The system 1 preferably has the capability to transmit the report via the network card 20 (and communication modem 30) to the remote computer 22 to be forwarded to the patient's physician.

Reference will next be made to Figures 3 through 22, which in conjunction with the following discussion will illustrate in detail the electronic microbiological worksheet and method according to the system 1 for conducting, recording and reporting microbiology 30 specimen testing.

The electronic worksheet system 1 comprises a software component (computer program 15 in Figure 1) which runs on the

workstations 10, as introduced above. When the workstation 10 is turned on, the electronic worksheet system 1 displays a Menu Screen 31 (Figure 3). The Menu Screen 31 is used by a technician to "log-on" onto to the system 1 and access the various features provided by the 5 system 1 as will now be explained.

The Menu Screen

Reference is made to Figure 3 which shows the Menu Screen 31 for the electronic worksheet system 1. The Menu Screen 31 is 10 displayed on the monitor 12 shortly after the system 1 (computer program 15) is started, and remains in computer memory (not shown) until the computer program 15 is terminated.

The Menu Screen 31 provides three primary functions. Firstly, the Menu Screen 31 is used for logging a user (typically a 15 microbiology technician) into and out of the electronic worksheet system 1 (block 218 in Figure 2 above). Secondly, the Menu Screen 31 displays the functions that the user (e.g. technician) is authorized to access. Thirdly, the Menu Screen 31 allows the functions of the electronic worksheet system 1 to be invoked.

As shown in Figure 3, the Menu Screen 31 comprises a number of objects which include a "Username" object 33, a "Password" object 35, a "Login" object (see below), a "Logout" object 36, a "Menu Options" list-box 37, an "Exit" object 38 and an "About" menu item 39. In the context of this description, the term object refers 25 to a command button, a menu item, an edit box, an input field, a listbox and any other "window" type software constructs, which are responsive to input from the computer keyboard 14, mouse 16 or barcode scanner 18.

The "Username" object 33 is an edit box. An edit box 30 allows text to be entered using the keyboard 14, for example. The technician enters his or her name using the keyboard 14 as part of the log-on process. The worksheet system 1 includes an administration

function in the computer program 15 which allows the user name(s) to be changed (when a user is not logged into the electronic worksheet system 1). See Figure 20 below.

The "Password" object 35 is also an edit box. If the user's name entered above is valid, the system 1 permits the user to enter his or her password which is then verified. The "Password" object 35 can also be manipulated using the administration function (when a user is not logged into the system 1). See Figure 20 below.

The "Login" object (not shown in Figure 3, but appears in same location as the "Logout" object 36) is a command button. When the "Login" command button is activated (e.g. by "clicking" the mouse), the computer program 15 will go through the following steps: validating the user's name and password; and if valid, displaying the functions (of the worksheet system 1) in the "Menu Options" list-box 37 which are accessible by the user. Once successfully logged in, the system 1 clears the entries in the "Username" edit box 33 and the "Password" edit box 35, and replaces the "Login" button (not shown) with the "Logout" command button 36. The system 1 activates the "Login" command button (appears in the same location as "Logout" button 36) when a user is not logged into the system 1.

When the user 'clicks' the "Logout" button 36, the computer program 15 will "log-off" the user from the electronic worksheet system 1. This will cause the "Logout" button 36 to be hidden and replaced by the "Username" 33, the "Password" 35, the "Menu Options" list-box 37 and the "Login" command button (not shown). It will be understood that the "Logout" command button 36 can be manipulated only when a user is logged into the worksheet system 1.

The "Menu Options" object 37 appears in the Menu 30 Screen 31 as a list-box. The computer program 15 uses the list-box to indicate which functions in the system 1 the user is authorized to access. Using the mouse 16 to click on any entry in the list-box will

cause the computer program 15 to invoke the associated function. The "Menu Options" list-box 37 is only responsive when a user has been logged onto the worksheet system 1. The various options in the "Menu Options" list-box 37 will be described in more detail below.

Lastly for the Menu Screen 31, the "About" object 39 is a menu item which appears near the top of the screen 31. In response to the "About" menu item 39 being clicked, the computer program 15 displays an "About" window (not shown) which provides information about the electronic worksheet system 1 (and computer program 15), such as copyright notice and version number for the program 15. The "About" menu item 39 can be manipulated or invoked at any time.

Typically, the technician will log-on onto the worksheet system 1 at the start of the workday and log-out at the end of the day.

However, the laboratory protocol may require the technician to also log-out and log-in during breaks, such as lunch. Assuming the technician has logged onto the electronic worksheet system 1 and is ready to begin testing specimens, the technician will click on "Observations" entry in the Menu Options list-box 37. In response, the system 1 (i.e. computer program 15) will display an electronic worksheet screen 40 as shown in Figure 4.

Reference is next made to Figure 4 which shows the electronic microbiological worksheet 40 that is produced by the system 1. The electronic microbiological worksheet screen 40 is displayed on the monitor 12 in response to clicking on the "Observations" entry in the "Menu Option" list-box 37 or in response to scanning the barcoded accession number on a test label. (The system 1 will display a dialog box message when the specimen is final reported and the "Observations" item was selected from the Menu window 31. This informs the user that results can be viewed but not changed.) The electronic microbiology worksheet 40 provides an interactive tool which is used by the technician to conduct the microbiological testing

and display and record the results of the testing. As shown in Figure 4, the electronic worksheet 40 comprises two windows. The first window is a patient demographic and specimen data window 42 which displays the demographic data for the patient from whom the specimen was taken. The second window is a microbiology test/observation window 44. The microbiology test/observation window 44 can comprise a Specimen Specific Test window 45 (see Figures 6(a) to 6(d) below) or an Observations window 47 (see Figures 7(a) to 7(e) below).

Before considering the electronic worksheet screen 40 in 10 detail, reference is made to Figure 5 which provides an overview of the steps involved in generating an electronic worksheet 40. The first test/observation window 44 that is displayed with the patient demographic window 42 is the Specimen Specific Test (SST) window 45 (Figures 6(a) to 6(d)) as indicated by block 228 in Figure 5. As will be 15 discussed below, the Specimen Specific Test window 45 is unique to the specimen type and allows the technician to generate a quick report. It is used primarily when the specimen has an insignificant or negative pathogen count. If there is a negative pathogen count (block 230), then the technician can use the SST window 45 to "default 20 report" the test to the physician (block 232). Because most specimens will have a negative result (i.e. no pathogens), the Specimen Specific Test window 45 provides an efficient technique for testing the specimen and quickly reporting to the patient's physician, as will be explained in greater detail below.

If there is a significant pathogen count present, the technician proceeds to the Observations window 47 in block 234. The Observations window 47 comprises a sequence of steps for identifying, i.e. "observing", the pathogen(s) and recording the results, i.e. "observations", thereof. These steps will be described in detail shortly. However, as an overview, the first step involves selecting the media type for the specimen (block 236). The technician then selects an observation which describes the pathogen (block 238) and is associated

with the selected media type. The system 1 gives the technician the option of entering a description of the pathogen (blocks 240, 242). If a description is entered, the technician has is given the option of entering a Quantifier in blocks 244,246, as will be explained in detail below.

The technician selects the status for the observation (block 248). The observation can be marked as USED, INFO or FROZEN. The USED status is selected when the technician wishes to perform further testing and work on a pathogen observed in the specimen. The INFORMATION status is used when the technician simply wishes to record the fact that something was observed, but does not wish to investigate further. The FROZEN status is used when the technician decides, for whatever reason, that the observation which was recorded was incorrect. The system 1 locks or freezes the observation for purposes of an audit trail.

Referring again to Figure 5, when the technician selects USED in block 250, the system 1 displays a Test Library Window (see Figures 11(a) to 11(g)) which is associated with that observation (as indicated by block 252). At this point, the technician may decide that the specimen should be sub-divided for further investigation (block 254). To sub-divide a specimen, the technician places a portion of the specimen on a new plate, slide or tube and binds (as will be described below) the new plate (slide or tube) to the observation in block 256. The technician then proceeds to the testing and recording in block 258.

25 Once testing (i.e. verification) has been completed, the technician will record a final identification for the pathogen that was observed (block 259). There may be instances where the technician will only record a partial identification in step 259 as will be discussed below.

If the technician wishes to perform additional observations for a specimen, then the technician selects an unused slot number in block 264. In response, the system 1 clears the input fields, and the technician proceeds through steps 234 to 258 for the new

observation. As will be discussed below, when the USED status is first selected, the system 1 automatically assigns the observation to slot number 1.

Referring still to Figure 5, if there are additional specimens to be tested (block 262), then the technician clicks the NEXT button which causes the system 1 to clear the electronic worksheet 40 thereby enabling the technician to scan the next specimen in order to retrieve the patient and specimen computer data file. On the other hand, if the technician has completed the testing and wishes to report the results, the technician moves to the Release Result Screen (see Figure 10 below).

Reference is now made back to Figure 4 which shows the details of the electronic worksheet screen 40. The patient demographic and specimen data window 42 comprises a number of display fields for 15 displaying the patient and specimen data file which was downloaded from the Laboratory Information System 26. Because the patient demographic data can be a tool for microbiological testing (e.g the sex and age of a patient), the system 1 will always display the patient demographic window 42 at the top of the microbiology electronic 20 worksheet screen 40. The patient window 42 includes a patient name field 101, a patient date of birth field 103, and a patient sex field 105, which all appear across the top portion of the window 42. Below the patient name field 101, there is a menu bar 107 which comprises a number of pull down command menus as will be explained below. The patient window 42 also has an accession number input box 109 and a number of display fields for displaying additional patient and specimen data.

In response to a valid accession number being entered in the accession number input box 109, the worksheet system 1 retrieves the patient demographic and specimen data file which has been downloaded from the Laboratory Information System 26 and stored in the microbiology database 28. The patient demographic and specimen

data is stored as part of a patient microbiology file which is produced by the system 1 and stored in the database 28. In addition to the patient and specimen data, the patient microbiology file will contain the test results and other testing information (once it is entered by the technician) as will be explained in more detail below.

The accession number for a patient can be entered manually from the keyboard 14 or by using the scanner 18 to read the bar-coded accession number on the test label which is attached to the specimen container (e.g. tube). After the specimen identifier 109 is 10 entered (and the user tabs off this field), the system 1 will perform the following steps: (1) the format of the specimen identifier 109 is validated and classified (i.e. is it an accession or a bar-code number); (2) an error message is displayed in a dialog box (not shown) if the validation step fails, and the system 1 will prompt the user to enter another specimen identifier 109; (3) if a bar-code number was entered, the system 1 will check whether the bar-code number exists in the database 28 (Figure 1). If the bar-code number exists, the system 1 will determine which specimen (number) is assigned ("owns") that barcode number; (4) display an error message in a dialog box if the bar-20 code number is not in the database 28, and prompt the user to enter another specimen identifier 109; (5) if an accession number was entered as the specimen identifier 109, the system 1 checks whether the accession number exists in the database 28. An error message is displayed in a dialog box if the accession number is not on file, and the system 1 prompts the user to enter another specimen identifier 109.

Once a valid specimen identifier 109 has been entered, the system 1 will allocate (i.e. reserve) the specimen number in the microbiology database 28. This is done to prevent multiple processes from simultaneously accessing information on the same microbiology specimen. The system 1 will display an error message in a dialog box if the system 1 is unable to allocate or reserve the specimen number, and the system 1 will prompt the user to enter another specimen

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identifier. Next, the system 1 will retrieve all information pertaining to the specimen from the database 28 (and any other data which is stored in computer memory and/or a temporary file located on the computer's disk).

The additional display fields include an "Accession:" field 111 for displaying the accession number; a "Physician:" field 113 for displaying the name of the patient's physician; a "Report to:" field 115 for displaying the physician's telephone number; a "Specimen:" field 117 for displaying the type of microbiological specimen; a "Source:" field 119 for displaying the source of the specimen; a "Status:" field 123 for displaying the status of the microbiological test; and a "Notes:" field 125. The Notes field 125 can be used by the physician to provide additional instructions or directions to the technician for testing the specimen. The patient window 42 also includes a bar-code pop-up 15 menu 127 for displaying any additional bar-coded specimen containers which have been "bound" to the accession number as will be explained below.

The Specimen Specific Test Window

Reference is next made to Figures 6(a) to 6(e) which show five exemplary Specimen Specific Test windows 45: a Genital Culture window 300; a Throat Culture window 320; a Stool Culture window 340; a Urine Culture window 360; and a General Culture window 370. The appropriate Specimen Specific Test window 45 (Genital 300, Throat 320, Stool 340 or Urine 360) is automatically displayed by the system 1 when an accession number is entered (i.e. through the keyboard 14 or bar-code scanner 18) and the status for the specimen is "Pending" as indicated by the Status field 123. The Specimen Specific Test class of windows are displayed on the electronic microbiology 30 worksheet 40 in a modal style as will be understood by those skilled in the art.

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The Specimen Specific Test window 45 is unique to a specimen type, e.g. genital culture 300, throat culture 320, stool culture 340 or urine culture 360 and is designed to provide an expeditious method for reporting non-significant or negative test results which are 5 observed by the technician. The technician uses the Specimen Specific Test class of window 45 to perform two primary functions. First, the Specimen Specific Test window 45 is used to input (and display) results for tests that are specific to a single specimen type, e.g. a urine sample. Second, the technician can use the Specimen Specific Test 10 window 45, e.g. the Urine Culture window 360, to default report (i.e. negative) specimens. It will be appreciated by those skilled in the field of microbiology that this is a very powerful and useful feature since the majority of microbiological specimens return negative or have non-significant pathogen counts.

The Specimen Specific Test class of window 45 can also be invoked in two other ways. Firstly, the Observation window 47 includes a SST command button 99 (Figure 7(a)). When the technician clicks the "SST" button 99, the system 1 will display an appropriate Specimen Specific Test (SST) window 45 in modal style. The system 1 uses the specimen type in determining which "SST" window is displayed. Secondly, a specimen type can be configured so that the appropriate Specimen Specific Test window 45 will be displayed (in a modal style) whenever a specimen is accessed via the Observation window 47.

Reference is made to Figure 6(b) which shows the Throat Culture window 320. The technician uses the Throat Culture window 320 to input and display test results and/or to report default results which are observed for a throat culture specimen. The Throat Culture window 320 includes a command button 322 labelled as "CF" 30 (Commensal Flora) and an "EXIT" command button 324. The CF button 322 is clicked for default reporting of bacterial flora which is insignificant. In response to clicking the command button 322, the system 1 toggles to default reporting the specimen. When the command button 322 is clicked, the system 1 adds an asterisk ("*") to the end of the caption on the command button 322 to indicate that the specimen will be default reported if the Exit button 324 is clicked. If the CF command button 322 is clicked again, the system 1 will remove the asterisk from the caption to indicate that the specimen will not be default reported when the Exit button 324 is clicked.

The Throat Culture window 320 also includes a messages list-box 326 and an array of check boxes 328 for Gram Stain 10 observations. The messages list-box 326 contains a list of "canned" or saved messages that can be used to default report the throat swab specimen. The messages stored in the list-box 326 are broken into two categories: (1) messages valid for the current specimen type; and (2) messages valid for all specimen types. Any message(s) selected from 15 the list-box 326 will appear beneath the list-box in a display field 327. When the exit button 324 is clicked, the system 1 will default report any messages that have been selected. Therefore, observation for a Throat swab specimen can be default reported using the CF (Commensal Flora) button 322 and/or through messages selected from 20 the list-box 326. The system 1 allows the message list-box 326 to be manipulated when: (1) the "Observations" option was selected from the Menu screen 31 (Figure 3); (2) the specimen has not been final reported; (3) no preliminary reports have been released to the Laboratory Information System 26; and (4) the microbiology file for the 25 specimen is not being retrieved for the first time from the microbiology database 28. When the specimen is default reported, the data associated with the mnemonic displayed on the command button 322 is typically sent to the Laboratory Information System 26.

The array of check boxes 328 is used to input and display results for the Gram Stain test. Each box 328 also includes a label which is an acronym identifying a typical result. The system 1 allows multiple boxes to be checked in the array 328. For example, the

technician can check the "YP" (Yeast Present) and "NVA" ("No Vincent's Angina) boxes in the array 328. The system 1 permits the check boxes to be manipulated when: (1) the "Observations" option is selected from the Menu screen 31 (Figure 3); (2) the specimen has not been final reported; and (3) the Gram Stain result hasn't been released to the Laboratory Information System 26.

Culture 340 and the Urine Culture 360 are similar to the Genital Culture window 300 and the Throat Culture window 320, with the following additional features. The Stool Culture window 340 includes a "Selenite subculture" panel 342 comprising two radio buttons 344,346 and a "Barcode" command button 348. The technician uses the "Selenite Subculture" panel 342 to input and display whether a Selenite subculture was performed on the stool specimen. Valid values for these radio buttons 344,346 are "YES" and "NO" respectively. In response to selecting "YES", the system 1 activates the "Barcode" command button 348, whereas selecting the "NO" button 346 deactivates the "Barcode" command button 348. The system 1 will accept inputs from the Selenite Subculture panel 342 when: (1) the "Observations" option was selected from the Menu screen 31 (Figure 3); and (2) the specimen has not been final reported.

Referring again to Figure 6(c), the system 1 uses the "Barcode" command button 348 to invoke a Bind Barcode window (Figure 13(a)). The technician uses the Bind Barcode window to "bind" or associate an additional plate, tube or slide with an observation. As will be explained below, the additional plate (tube or slide) contains a portion of the specimen for further identification of an observed pathogen or organism. The system 1 displays the Bind Barcode window in a modal style. The system 1 allows the technician to use the "Barcode" command button 348 when: (1) the "Observations" option is selected from the Menu screen 31; (2) the specimen has not

been final reported; and (3) the selenite subculture radio button 344 has been set to "YES".

As discussed above, the Throat Culture window 320 (and other Specimen Specific Test windows) include an "Exit" command 5 button 324 (Figure 6(b)). When the Exit button 324 is clicked, the system 1 exits the Specimen Specific Test window, e.g. Urine Culture window 320, and updates the microbiology record for the specimen in the database 28 with any changes. If the specimen is being default reported, then the system 1 updates the patient microbiology record 10 (corresponding to the accession number in field 111 (Figure 4)) in the microbiology database 28 is updated and the system 1 sends the test result data to the Laboratory Information System 26. The system 1 then clears all information (e.g. patient demographic and specimen data) about the current specimen from the electronic worksheet screen 40 and the system 1 returns control to the accession number input box 109 on the electronic microbiology worksheet 40. If the specimen isn't being default reported, the system 1 displays the Observation window 47 as will be explained below with reference to Figure 7. The system 1 does not clear the patient demographic and specimen data in the worksheet screen 40.

The Specimen Specific Test class of windows can also include the "General Cultures" SST window 370 and a "Blood and Fluid Cultures" SST window. The General Cultures window 370 comprises a SST window 45 which incorporates the commands and fields common to the SST class of windows for a miscellaneous specimens, i.e. specimens which do not fall into pred-defined groups such as urine, throat or stool, for example, a sputum specimen. An exemplary General Cultures SST window 370 is shown in Figure 6(e). The "Blood and Fluid Cultures" window, on the other hand, is specific to blood and bodily fluid specimens and includes command buttons for reporting test results and default reports specific to blood and other

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fluid specimens, in a manner similar to that described above, for the other SST class of windows.

The Observations Window

Reference is next to made to Figures 7(a) to 7(j) which show in detail various aspects of the Observations window 47 in the electronic microbiology worksheet 40 which is generated by the system 1. The Observations window 47 is used to view, record and/or modify identified organisms or pathogens on the specimen which are observed by the technician. For example, if a pathogen is observed, the technician will exit from the Specimen Specific Test window 45 (see above) and conduct more specific tests as provided in the Observations window 47. One of the purposes of these further tests is to verify the identification of the pathogen which was observed earlier.

As shown in Figure 7(a), the Observations window 47 comprises numerous objects which are used to guide and record the observations of the technician. The Observation window 47 is designed to display all the information associated with an observation of a pathogen for a microbiological specimen. A feature of the system 1 20 is that more than one observation (i.e. the presence of a pathogen or organism) can be associated with a specimen. The system 1 has the capability to assign twelve observations to a particular specimen (or accession number). Each observation is designated by a slot number. The slot numbers appear as an array 52 comprising twelve slot 25 number command buttons 53. The command buttons 53 are labelled "1" to "12". In response to clicking a slot button 53, the system 1 displays the nth observation belonging to the current specimen. The buttons 53 are active only when a specimen is displayed in the Observation window 47. The label on the slot button 53 corresponds 30 with the observation number that will be displayed when the button is clicked. For example, clicking the slot "5" button 53 will display the 5th observation. When the patient microbiology record associated with a

specimen is retrieved from the microbiology database 28, only n+1 command buttons 53 are active (where n is the number of observations that belong to the specimen). For example, buttons 1-6 are active for a specimen with 5 observations. In response to the technician clicking the n+1 command button, the system 1 opens a new observation except when the specimen has been final reported or the "Review" option was selected from the Menu screen 31. The slot buttons 53 for the slot numbers are available whenever a specimen is displayed on the Observation window 47.

The Observation window 47 includes a "Media" edit/list-box 80, which indicates the type of media for the specimen, e.g. slide. When a command button 80b is clicked, the system 1 displays the media list 80 as a list-box 80d (see Figure 7(b)). The technician will look at the media type for the specimen to be tested and then select the appropriate media type from the list-box 80d. The selected media type is then displayed in the Media box 80. Since different kinds of specimens require different growth media, the usefulness of this feature will be appreciated by one skilled in the art.

box 82. The technician uses the Observation box 82 to input (i.e. record) the observations of the specimen. The Observation box 82 has a command button 82b which when clicked causes the system 1 to display an Observations list-box 82d (see Figure 7(c)) which lists observations. The "Observation" box/list-box 82d is populated with observations based on the selected media plate and specimen type (for examples see Figure 7(b)). The observation is of the nature "Looks like", followed by a description. (As will be explained below, the system 1 requires the technician to verify the observation by performing one or more tests from a selected test library.) Typically a list of about thirty observations (each identified by its initials) is made available to the technician, arranged in order of likely appearance based on the type of the media, with the most likely observation appearing first in the

Observations list-box 82d. All keyboard 14 input sent to this object is ignored - the only way to select a item is via the mouse 16 (i.e. by pointing and clicking). The system 1 allows the technician to manipulate the "Observation" box 82 when a specimen is displayed; the "Observations" option is selected from the Menu window 31; the current observation's state is "FREE"; and a media type has been selected in the "Media" box 80.

Referring back to Figure 7(a), next to the Observation box 82, there is a "Description" box/list-box 84. The "Description" box 84 10 provides a list of descriptive qualifiers which the technician can select from a Descriptions list-box 84d as shown in Figure 7(d). The Descriptions list-box is activated by clicking a command button 84b. The list-box 84d is populated with the most likely qualifiers or descriptions based on the selected observation (for examples see Figure 7(d)). Again there is a list of descriptions (e.g. "grey", flat", etc.) for each observation. The system 1 ignores all input from the keyboard 14 in making selections for the Description box 84. The only way to select a item is via the mouse 16 from the Descriptions list-box 84d. The system 1 allows the technician to manipulate the contents of the 20 "Description" box 84 when a specimen is displayed; the "Observations" option was selected from the Menu window 31; the current observation's state is "FREE"; and an observation has been selected in the "Observation" box 82.

Next to the "Description" field 84, there is a "Quantifier"

25 box 86. The Quantifier box 86 includes a command button 86b which is used to display a Quantifier list-box 86d (Figure 7(e)). The Quantifier list-box 86d provides an input or object for specifying the quantity of pathogen on the specimen plate. The Quantifier list-box 86d allows the technician to select the appropriate value that quantifies the observation. The "Quantifier" list-box 86d is populated with quantifiers based on the selected observation. The quantifier will typically be a list of one, two, three, or four plus signs or other

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appropriate symbols to indicate the quantity of the item which is observed. The system 1 ignores all input from the keyboard 14 in making selections for the Quantifier box 86. Input must be entered by selecting an item via the mouse 16.

As discussed above, the "Media" box/list-box 80,80d is populated with a list of different types of media based on the current specimen type being viewed, for examples, see Figure 7(b). All keyboard input sent to the Media box 80 is ignored - the only way to select a media item is via the mouse 16 (i.e. by pointing and clicking) 10 from the Media list-box 80d. When a new media type is selected, the system 1 clears any data in the "Observation", "Description" and "Quantifier" boxes 82,84,86, and the "Observation" list-box 82d (Figure 7(c)) is populated with a new list of observations which are valid for the selected media (as will be described).

To proceed with the testing procedure, the system 1 requires that the technician enter a media type (Media box 80) and an observation (Observation 82). Entries in the Media box 80 and the Observation box 82 are compulsory. On the other hand, the technician has the option of making an entry in the Description box 84 and the 20 Quantifier box 86. When a new observation is selected, the current entry displayed in the Observation box 82 loses focus (because only one observation can be worked on at a time), and the system 1 clears any entries in the "Description" and "Quantifier" boxes 84,86, and populates the list-boxs 84d,86d for these boxes with a list of descriptive qualifiers and a list quantifiers valid for the selected observation, which can then be manipulated by the technician upon further observation of the specimen.

Beside the Quantifier box 86, there is a specimen "State" button 87 (Figure 7(a)). The technician will manipulate the State 30 button 87 after entering the media type (box 80) and the observation type (box 82), and optionally the description and quantifier (boxes 84,86). In response to the State button 87 being clicked, the system 1 a

"Statelb" list-box 87d (Figure 7(f)) to display a list of the "states" for an observation. The system 1 provides four states for an observation; (1) FREE; (2) USED (as shown in Figure 7(a)); (3) INFO; and (4) FROZEN, as shown in Figure 7(f).

The FREE state is the default state. It indicates that the observation has not been committed, and the system 1 will allow the technician to makes entries in the Media, Observation, Description and Quantifier boxes.

The USED state signifies that an observation has been made and is intended to be reported (i.e. released to the patient's physician). In the USED state, the system 1 will not permit the values in the Media, Observation, Description and Quantifier boxes to be changed. The technician selects this state in order to work on an observation. In response to selecting this state, the system 1 will display the appropriate Test Library window 76 (see below).

The INFO state indicates that an observation has been made but is not intended to be reported. In the INFO state, the system 1 prevents the technician from changing the entries in the Media, Observation, Description and Quantifier boxes. This state is selected, for example, when the technician wants to record clinically insignificant information but not perform any follow up work.

The FROZEN state signifies that an erroneous observation has been made (e.g. a technician/technician in training) and therefore should not be reported. The system 1 still retains or "freezes" the entries in memory in order to produce an audit trail.

The system 1 will permit the technician to change a "FREE" observation to USED, INFO or FROZEN. A "USED" observation can be changed to INFO or FROZEN. An "INFO" observation can be changed to "USED". A "FROZEN" observation can be changed to "USED".

As will be understood by one skilled in microbiology, each microbiological growth, e.g. pathogen or organism, observed on a

"Media" plate can be categorized into one of several test libraries. Each library contains specific tests that, when performed, will aid the technologist in identifying or confirming the identification of the observed organism or pathogen. Each library is represented by the window 76 which is displayed at the bottom of the Observations window 47. The system 1 includes logic for applying microbiology rules to determine which test library should be displayed for the entry in the Observation box 82.

As soon as the technician clicks the state button 87, the system 1 will display a Test Library 76 (Figure 7(a)). The system 1 does not display the Test Library 76 if the INFO or FROZEN state is selected. The Test Library 76 comprises a list of tests that are uniquely associated to the selected observation (box 82). Typically, even if there are more observations to be entered for a specimen, the technician will click USED for the current observation and begin the tests for that observation, and then afterwards, the technician will move to the subsequent observation(s).

The Test Library 76 which is shown in Figure 7(a) is unique to the selected observation, i.e. "STAPH", in the Observation 20 box 82. For example, the Test Library 76 includes a "Replianalyzer" test 77 which can be used to test for the STAPH pathogen. As shown, the Replianalyzer test 77 includes a "YES" radio button 79a and a "NO" radio button 79b for recording the result of the test for the STAPH organism. Even if the technician "knows" what the observed 25 pathogen is, the system 1 requires that one or more test be conducted to prove the truth of the technician's identification. (Otherwise, the system 1 will not allow the observation to be reported to the physician.) Therefore, the technician will always select and conduct one or more tests from the Test Library 76 that he or she feels is appropriate for the observed organism. Additional test libraries are discussed below with reference to Figures 11(a) to 11(g).

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Conducting the test(s) selected from the Test Library 76 normally requires additional plates, slides or tubes on which a portion of the original specimen is placed. To keep track of and associate these additional plates, slides or tubes with the observation number (and the 5 patient/specimen data), the system 1 includes a "Binding" feature.

As shown in Figure 7(a), the Menu Bar 107 includes a "Bind" command 56. In response to clicking the Bind command 56, the system 1 displays (in modal style) a "Bind Barcode" window 550 as shown in Figure 13(a). The Bind Barcode window 550 can also be 10 accessed by clicking a "Barcode" command button on certain selected Specimen Specific Test windows, for example, the Stool Culture window 340 in Figure 6(c). This is a useful feature because certain specimens, e.g. a stool sample, by their nature will require additional plates (tubes or slides) for testing.

In the preferred embodiment of the present invention, each specimen plate (slide or tube) has its own bar code identifier, and this bar code identifier is used to cross-reference or "bind" the additional plate (slide or tube) to the original accession number (and patient and specimen data file). The effect of using bar-coded plates 20 (slides or tubes) is that in response to the technician scanning a barcoded plate which has been "bound", the system 1 will display the electronic worksheet 40 (including the patient information) for the accession number associated with the plate bar-code. Furthermore, scanning the bar-coded plate can also be used to retrieve the particular 25 observation associated with that bar-code and accession number. It will be appreciated that this feature allows the electronic information (stored in the microbiology database 28 and Laboratory Information System 26) to track and be available when the physical specimen plates are tested at the workbenches.

The relationship between the plate bar-codes and the accession number bar-code is illustrated in Figure 13(b). The technician can quickly view all the bar-codes which have been bound to a

specimen (and accession number) by clicking the bar-code icon 127 in the patient and specimen data window 42. In response to clicking the bar-code icon 127, the system 1 displays a list-box 127d (as shown in Figure 7(j)) of all bar-codes associated with the specimen currently being displayed. As discussed above, a specimen is identified in the microbiology laboratory (and the remote computer 22) by a bar-code which corresponds to the accession number. Once in the microbiology laboratory, additional plates, slides or tubes can be associated with the original specimen (and accession number). If the bar-code is associated with a specific observation number, then the system 1 displays the observation number beside the bar-code number in the list-box 127d. The system 1 only activates the bar-code icon 127 when a specimen is being displayed.

Referring to Figure 13(a), the Bind Barcode window 550 includes a "Barcode #" edit box 552, an "Option" panel 554, a "DO IT!" command button 556, and an "EXIT" command button 558.

The technician uses the "Barcode#" box 552 to enter the bar-code number (on the plate) which is to be bound (or unbound) from an accession number. The bar-code number can be entered via the keyboard 14 or by using the scanner 18 to read the bar-code on the plate/tube label. The actual bar-code number appearing on the label can be assigned by the Laboratory Information System 26 or supplied by the technician. In the preferred embodiment, the barcode is 6 or 9 digits in length.

The "Option" panel 554 comprises a "Bind" radio button 555 and an "Unbind" radio button 557. In response to the technician clicking the "Bind" button 555, the system 1 will be enabled to bind the bar-code number (contents of box 552) to the current observation number (for the specimen). Conversely, in response to clicking the "Unbind" button 557, the system 1 will be enabled to "unbind" or disassociate the bar-code number from the current observation. The system 1 allows the technician to manipulate the "Option" panel 554

when a valid bar-code number has been entered into the "Barcode#" box 552.

Referring to Figure 13(a), the "Do it" command button 556 binds (or unbinds) the bar-code number to (or from) the current observation, depending on which radio button 555 or 557 has been activated. In addition, the system 1 makes the following checks when the technician binds a bar-code: (1) ensuring that the bar-code number isn't already used for the current specimen or any other specimen; (2) the bar-code exists in the microbiology database 28; (3) ensuring that the bar-code is bound to the current observation of the specimen. The system 1 will display an error message in a dialog box (not shown) if any of these checks fail.

Referring still to Figure 13(a), assume for example that the technician is working on Observation number 1 (i.e. slot number 1) and one or more tests (from the Test Library 76) have been selected. The technician then selects the required number of plates (slides or tubes) as required for the particular test (e.g. Novobiocin) and clicks on the "Bind" command to display the Bind Barcode window 550 and then clicks the Bind radio button 555. The technician scans the barcode on each extra plate (slide or tube) and clicks the "DO IT!" button to bind the barcode of the extra plate to Observation number 1. This is repeated for each extra plate, tube or slide which is to be used for Observation number 1. Once the extra plates, tubes or slides have been bound, the technician conducts the additional tests (in the Test Library 76) to verify identification of the observed organism.

After conducting the additional testing, the technician can make a final identification of the observed pathogen or organism or a partial (preliminary) identification. To record these identifications, the Observation window 47 includes an "ID and Sensi" panel 94 as shown in Figure 7(a).

The ID and Sensi panel 94 has a "Sensi" input box/droplist 96, a Partial ID input box/list-box 98, and a Final ID input box/listbox 100. Each of the boxes 96,98,100 becomes a list-box, denoted by references 96d, 98d and 100d, when a respective command button 96b,98b,100b is actuated as shown in Figure 7(a). The technician then selects an entry from the active drop-list. The system 1 ignores all input from the keyboard 14 for the Partial and Final ID boxes 98,100 (and the Sensi box 96), and the technician can only make an entry using the mouse 16 to select an item from the list in the list-box. Because there may be an organism which is not listed, each of the list-boxs for the Sensi, Partial and Final ID boxes 96,98,100 includes a "Free Text" entry which allows the technician to enter an organism name directly from the keyboard 14. See Figure 7(g) for the Sensi list-box 96d, Figure 7(h) for the Partial ID list-box 98d, and Figure 7(i) for the Final ID list-box 100d.

Referring to Figure 7(h), the Partial (or preliminary) ID list-box 98d contains a list of valid organism names based on the selection in the Observation box 82. The technician will typically use the Partial ID box 98 where the doctor has asked for a preliminary result (which can be indicated in the "Notes" field 125 of the patient and specimen data window 42), or where the technician has identified a species of pathogen, but has yet to determine the type, e.g. a STAPH organism. The system 1 permits the technician to change the entry in the Partial ID box 98, whereas the entry in the Final ID box 100 cannot be changed.

The system 1 allows the technician to manipulate the Partial ID box 98 under the following conditions: (1) a specimen is displayed; (2) the "Observations" option has been selected from the Menu window 31; (3) the specimen has not been final reported, i.e. the final identification of the organism has not been released to the doctor; (4) the observation's state is "USED"; and (5) the partial identification (i.e. entry in Partial ID box 98) has not been released to the Laboratory Information System (the remote computer 22).

Similarly, the Final ID list-box 100d (as shown in Figure 7(i)) also contains a list of valid organism names based on the entry in the Observation box 82. The system 1 ignores all input from the keyboard 14 for this box, and the technician must use the mouse 16 to select an item from the list in the list-box. However, by selecting the Free Text entry, the technician can use the keyboard 14 for directly entering the organism name. Unlike the Partial ID box 98, the Final ID box 100 cannot be changed directly once the Observation window 47 is exited. The technician can however start over by "Freezing" the observation using the State button 87.

The system 1 allows the technician to manipulate the contents of the Final ID box 100 when: a specimen is displayed; the "Observations" option is selected from the Menu window 31; the specimen has not been final reported; the observation's state is "USED"; and the final identification (i.e. item from Final ID box 100) has not been released to the Laboratory Information System. If the Partial ID box 98 does have an entry, the system 1 will automatically copy the selected final identification into the Partial ID box 98.

There may be instances where the patient's doctor has requested that the test results be telephoned as soon as they are completed. The technician can use the telephone icon 104 to display/set whether the microbiology test results have been called to the physician. (Documentation of telephone reporting is mandatory in some jurisdictions.) A direction to call the physician can be included in the Notes field 125 which is downloaded from the Information System 26. In response to clicking, the system 1 toggles the display of the icon 104 between a telephone with two red diagonal lines across it (i.e. results not called) and a telephone without the diagonal lines (i.e. results were called to the physician). The default state for the icon 104 is a telephone with two red diagonal lines across it (i.e. results not called). If the test results for the specimen have been final reported (see

Result Release screen below), then system 1 will not allow the technician to manipulate the telephone icon 104.

As discussed above, the type of observed pathogen or organism observed will determine the type of microbiological testing which must be done to verify identification of the pathogen or organism. Once the pathogen or organism has been verified, the observation (i.e. pathogen identity) and source of specimen (i.e. location on human body) can be used to determine an appropriate antimicrobial agent for killing or retarding the bacterial pathogen or organism. To help the technician choose an appropriate antimicrobial agent for the observed pathogen, the Observation window 47 includes an antibiotic susceptibility panel which is indicated by the broken outline 88 in Figure 7(a).

The Antibiotic Susceptibility panel 88 comprises a series of individual radio button sensitivity indicators 92. The system 1 will only display those sensitivity indicators 92 which are appropriate for the entry in the Sensi box/list-box 96. The system 1 will determine the list of entries in the Sensi list-box 96 according to the entries in the Observation box 82 and the Media box 80. In other words, the system 1 uses the contents of the Observation and Media boxes 80,82 to determine which sensitivity indicators 92 should be displayed.

Referring to Figure 7(a), the Antibiotic Susceptibility panel 88 comprises a series of three letter (mnemonic) labels 90 which each identify type of antibiotic and are arranged in columns. The sensitivity indicators 92 are located below each mnemonic 90. (As discussed above, the system 1 will only display those sensitivity indicators 92 which are valid for the observation thereby simplifying the technician's work.) The sensitivity indicator 92 comprises an array of three vertically stacked radio buttons 93 signifying "Sensitive" (displayed in the colour red), "Resistant" (displayed in the colour green), and "DNR" (Do Not Report - displayed in black). For example, the technician would select DNR if the antibiotic is inappropriate for

the age group of the patient. The radio buttons 93 are used to display or modify the sensitivity result for a specific antibiotic (indicated by the mnemonic 90). The system 1 will not allow the technician to manipulate a sensitivity indicator if the specimen (test result) has been 5 final reported.

Another feature of the Antibiotic Susceptibility Panel 88 is that the label "Sensitive" 95 is an active object. In response to the technician clicking on the label "Sensitive", the system 1 will report the settings of each indicator 92 without a result as sensitive. In addition, if a radio button 93 in the sensitivity indicator 92 is selected when there is an identification in the Partial or Final ID boxes 98 or 100, the system 1 will apply any microbiology rules which are associated with that antibiotic, and the system 1 will display a dialog box (not shown) if the rule fails. The system 1 thereby notifies the technician that there is an inconsistency.

The steps involved in testing/verifying an observed pathogen in the specimen (i.e. an observation) are summarized in flow chart form in Figure 8. To verify the identity of a pathogen which has been observed on the specimen, the technician displays the Test Library which is associated with the particular observation (block 252 in Figures 5 and 8). Most tests require that the technician prepare an additional plate, slide or tube containing a portion of the specimen (shown as blocks 254,256 in Figures 5 and 8). The additional plate (slide or tube) is bound to the observation using the Bind Barcode function of the system 1 (block 256 in Figures 5 and 8).

Once the additional specimen plate has been prepared, and incubated if necessary, the technician selects one or more tests from the Test Library Screen and performs the test according to the test protocol (blocks 700 and 702 in Figure 8). If the results of the testing are non-significant or negative, the technician can choose to go back to the Specimen Specific Test screen 45 (block 704) by clicking the SST command button 104 on the Observation window 47 (block 706).

However, as discussed above, the system 1 will not allow the technician to return to the SST screen 45 from the Observation window 47 unless the technician "freezes" the information already recorded for the observation presently under consideration (block 708).

It will be remembered that once an observation has been frozen, it cannot be reported as positive. Therefore, the system 1 will allow the technician to move back to the Specimen Specific Test screen 45 to report the negative result. As discussed above, the Specimen Specific Test screen 45 provides an expedient method of reporting negative test 0 results.

Referring again to Figure 8, if the technician does not decide to freeze the observation, i.e. the test result is positive, then the next step involves making an entry in the Partial ID box 98, if requested by the patient's physician, (blocks 706,708). This is typically 15 done if the physician needs a preliminary identification, but would like further testing to be done on the patient specimen. Once the selected test or tests have been done, the identification of the observed pathogen should be established. At this point, the technician will record the identification of the observed pathogen in the Final ID box 100 (Figure 7(a)) in block 710. The technician will then display the Antibiotic Susceptibility Panel 88 (Figure 7(a)) to determine one or more suitable antimicrobial agents for killing the identified pathogen (block 712). As discussed above, the system 1 will apply predetermined microbiology rules to help the technician determine a suitable for antibiotic. If the physician has requested a telephone report (block 714), then the technician will "phone-in" the results (i.e. partial or final identification) and click the telephone icon 104 (Figure 7(a)) to indicate that this has been done (block 716). The technician then moves to the next observation for the specimen in step 260 (Figures 5 and 8).

There will be instances when there is not enough specimen material on a plate (slide or tube) for the technician to do the test or the portion of the specimen under observation may have been

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adulterated. In these instances, the technician will typically prepare a "Media" purity plate by dipping a wire into the desirable part of the specimen colony and streaking the wire on a new plate which is then incubated. Once the specimen on the purity plate has undergone incubation, the technician can continue with the test.

To record the purity plate with the observation, the Observation window 47 includes a "Purity Plate" command button 110 as shown in Figure 7(a). The technician clicks the Purity Plate button 110 to record preparing the purity plate. (In response to the technician clicking the button 110, the system 1 will toggle the caption between "NO" (default) and "YES".) The physical purity plate is then bound to the observation using the "Bind" command 56 (Bind Barcode Screen 550 shown in Figure 13(a)). If the purity plate was prepared after the technician made an entry for an observation slot (e.g. observation no. 1), then the observation for the purity plate colony is simply entered in a free observation slot (e.g. observation no. 2).

In some instances when the purity plate is incubated for an observation, there will be two types of pathogens or bacteria present and both will be related to the observation number. In this case, the technician can subdivide the purity plate into a subculture. If one of the subdivisions requires further culturing, the technician can do this using a subculture plate. The Observation window 47 includes a "Sub Cult" command button 112 for recording that there is a subculture for an observation number or slot. The technician will also bind the subculture plate to the observation using the "Bind" command 56 (as discussed above). A subculture is typically done when a pathogen or bacteria cannot be readily identified by the technician. Once the subculture is incubated, it is treated like any other specimen being tested using the system 1, i.e. there will be a subculture observation slot, media and observation entries, test libraries etc.

When the technician clicks the Sub Cult button 112, the system 1 displays (in modal form) a Subculture-Slot window 620 as

shown in Figure 18. The Subculture-Slot window 620 allows the technician to select which subculture observation slot to which the subculture is assigned. As shown in Figure 18, the Subculture-Slot window 620 comprises an array of slot number command buttons 622, an execute command button 624, and a cancel button 626.

The slot number buttons 622 comprise a set of twelve slots which constitute subdivisions of the observation number from which the subculture originated. The system 1 will permit an observation to be sub-cultured to any observation, other than itself, 10 whose state is "USED". The system 1 will only enable those command buttons that meet this criteria, for example, slot numbers 2 to 5 in Figure 18 are enabled. When the technician clicks the "OK" command button 624, the system 1 will assign the sub-culture observation number (a selected slot is indicated by an outline 628) associated with 15 the current observation number, and will close the Subculture screen 620 and return control to the Observation window 47 (Figure 7(a)). In response to technician clicking the "Cancel" button 626, the system 1 will close the Subculture window 620 and return control to the Observation window 47, but no changes are made to the observation.

The steps involved in preparing a purity plate and/or sub-culture are summarized in flow chart form in Figure 9. If the technician wishes to prepare a purity plate (block 800), the technician allocates a portion of the specimen to a purity plate (block 802). The technician then clicks the "Purity Plate" command button 110 on the 25 Observation window 47 (Figure 7(a)) and the system 1 records a purity plate (block 804). The next step involves "binding" the physical purity plate to the observation (block 256). This done through the "Bind Barcode" command 56. Once the purity plate has been prepared and bound to the observation, and if necessary incubated, the technician continues with the testing as discussed above. If the purity plate was prepared under observation slot no. 1 and the technician had already entered results, then the technician can freeze the information in

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observation no. 1, and use observation no. 1 for the new results observed on the purity plate.

Referring again to Figure 9, if the technician wishes to sub-culture the specimen (block 806), then the technician will allocate a portion of the specimen to a subculture plate (block 808). The technician will subculture or sub-divide a specimen, if for example, the purity plate contains two types of pathogens that are related to an observation (e.g. no. 1), or if the pathogen on the cannot be readily identified by the technician. To record the sub-culturing of a specimen, the technician clicks the "Sub Cult" command button 112 (Figure 7(a)) in block 810, and in response the system 1 toggles the caption on the command button 112 to "YES". In addition, the system 1 displays the Subculture window 620 (Figure 18) as was discussed above. The technician then binds the physical subculture plate to one of the subculture observation slot numbers using the "Bind Barcode" command 56 (Figure 7(a)) as indicated in block 256.

Referring back to Figure 7(a), the Observation window 47 also includes a "Gram Stain" box/list-box 106. There will be instances where the physician will request a "gram stain", for example, to verify a specific type of bacteria. The "Gram Stain" box 106 displays a list of valid results for a gram stain test when a command button 108 is clicked using the mouse 16.

Lastly with respect to Figure 7(a) reference is made to the menu bar 107. The menu bar 107 comprises a "Release" command object 54; a "Bind" command object 56; a "Status" command object 58; a "Messages" command object 60; a "Print" menu item 62; a "Review" command object 64; and an "Exit" command object 66. The "Bind" command 56 has already been discussed above with reference to the Bind Barcode screen 550 in Figure 13(a).

The technician uses the "Release" object 54 to display the Release Screen 400 (Figure 10) which will be explained in detail below with reference to Figure 10. The system 1 will disable the "Release"

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command 54 if the technician is not authorized to release test results. In addition, the system 1 will disable the Release command 54 if the specimen has been final reported, i.e. the results have already been released.

The "Status" command object 58 is used by the technician to access a Slot Status Screen 600 (Figure 17). The system 1 will allow the technician to access the Slot Status Screen 600 if a specimen is currently being displayed.

Reference is next made to Figure 17 which illustrates the Slot Status Screen 600. The system 1 uses the Slot Status Screen 600 to display the current state (FREE, USED, INFO, or FROZEN) and status (completed or pending work) of each observation. The system 1 displays this screen in a modal style when the technician clicks the "Status" command object 58 on the Observation window 47.

As shown in Figure 17, the Slot Status Screen 600 comprises a display-box 602 and an "Exit" command button 604. The display-box 602 is divided into a Slot Number column 606, a State column 608, and a Status column 610.

The display-box 602 provides a static display of the state and status of each observation. When the Exit button 604 is clicked, the system 1 closes the Slot Status window 600 and returns control to the Observation window 47.

Referring back to Figure 7(a), the "Messages" command item 60 is used by the technician to access a Messages Screen (Figure 15). The function of the Messages screen 570 is to display any canned messages or free-text comments that were released from the Result Release window 400 (see below and Figure 12). The system 1 displays the Messages screen 570 in a modal style when the technician clicks the "Message" command item 60 on the Observation window 47.

As shown in Figure 15, the Messages screen 570 has a display-box 572 and an "Exit" command button 574. The display-box 572 provides a static display of any canned messages or free-text

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comments associated to the current specimen. When the technician clicks the "Exit" command button 574, the system 1 closes the Messages screen 570 and returns control to the Observation window 47 (Figure 7(a)).

The system 1 makes the "Messages" command 60 available when a specimen is currently being displayed and one or more test results for the current specimen have been released (i.e. uploaded to the remote computer 22). When the "Messages" menu item 60 is not available, it is "greyed out" by the system 1 as shown in Figure 7(a).

Reference is next made to the "Print" command item 62 in Figure 7(a). In response to the technician clicking the "Print" menu item 62, the system 1 displays a "drop-down" print menu (not shown) to enable printing of information about a specimen and/or observation. The system 1 makes the "Print" command item 62 available when a specimen is currently displayed.

In the preferred embodiment of the present invention, the drop-down print menu (not shown) comprises an "Observation" menu item (not shown) and a "Specimen" menu item (not shown). In response to the technician, clicking the "Observation" menu, the system will print a report on the default printer (for example, printer 19 in Figure 1). The report contains information pertaining to the observation currently being displayed. The "Observation" menu item (not shown) is available when a specimen is currently displayed. The "Specimen" menu item (not shown) is also used to print a report on the default printer. The report contains complete information pertaining to all observations of the current specimen. The "Specimen" menu item is available when a specimen is currently displayed.

Reference is next made to the "Review" command item 64, which is shown in a deactivated state in Figure 7(a). In response to

the technician clicking the "Review" menu item 64, the system 1 will display a Review Screen 580 (Figure 16).

The Review Screen shown in Figure 16 allows the technician to spot check final reported specimens. The system 1 uses the Review screen 580 to assemble a list of specimens that were final reported on a specific date and belong to a specific specimen type. For example, the screen 580 in Figure 16 shows all throat specimens that were final reported on "May 3rd 1993". The technician can then select a specimen from this list and it will be displayed on the Observation window, as will be explained below. The system 1 displays the Review window 580 in a modal style when the technician clicks the "Review" command item 64 (Figure 7(a)).

As shown in Figure 16, the Review screen 580 comprises an Accessions display-box 582, a Date box 584, a Specimen Types list-box 586, a Find command button 588 and an Exit command button 590.

The system 1 uses the Accessions display-box 582 to display a list of accessions that were final reported on the selected date (box 584) and are of the selected specimen type (as per Specimen list-box 586). In response to the technician clicking one of the accessions, the system 1 will close the Review window 580 and display the selected specimen on the Observation window 47.

The Date box 584 comprises a spin control element which is incremented or decremented to display the desired final report date. The "Specimen Types" box 586 contains a list of all valid specimens types in microbiology database 28. For a query, at least one specimen type must be selected. The "Find" command button 588 allows the user to search for all specimens of the selected specimen type that were final on the selected date, and these specimens are displayed in the accessions display-box 582. Lastly, the "Exit" button 590 is clicked to close the Review window 580 and return control to the Observation window 47.

Reference is next made to the "Exit" command item 66 shown in Figure 7(a). In response to the technician clicking on the "Exit" command item 66, the system 1 will exit the electronic worksheet 40 (and Observations window 42) and return control to the Menu screen 31. If a specimen is currently being viewed, clicking on the "Exit" menu item 66 will cause the system 1 to update the database 28 (Figure 1) with any changes made by the user, clear all specimen related information displayed on the electronic worksheet 40, and close any test library windows. The "Exit" command item 66 will be available anytime the "Observations" window 42 is being displayed.

Lastly with reference to Figure 7(a), if an accession number (specimen identifier 109) is used to retrieve the specimen, then the system 1 will display the information associated with observation no. 1. The slot number of the current observation being displayed is indicated by a display field 55 which is shown in broken outline and labelled "Observation:". (As shown in Figure 7(a), the information entered for observation slot number 1 is being displayed in the Observation window 47.) On the other hand, if a bar-code number (which was bound to the accession number) was used to retrieve the specimen information from the database 28, then system 1 will display the observation number that is associated with the bar-code number being displayed. If the bar-code number is not associated with a specific observation number (e.g. a bar-code on a media plate), then the system 1 will display observation no. 1.

Once the Partial/Final IDs, Sensitivities and other information for the observations have been entered, the technician will review the information before going to the Result Release Screen 400 (Figure 10). If there are any sub-cultures associated with an observation and the sub-culture observation is to be released, then the technician must transfer the information from the sub-culture observation to an unused observation slot (as selected from the observation slot panel 52). The technician can then proceed to the

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Result Release Screen 400 by simply clicking the "Release" command 54 in the menu bar 107.

Result Release Screen

Reference is next made to Figure 10, which shows the Result Release Screen 400. The technician uses the Release screen 400 to release results to the Laboratory Information System 26 on the remote computer 22. The Release screen 400 allows the information associated with the observations to gathered in a format which can be reported to the patient's physician. Since observations can be entered in any order, e.g. order of appearance, and not necessarily order of importance, the Release screen 400 provides the capability to select and format the observations for release to the physician.

The Release screen 400 is displayed when the technician clicks the "Release" menu item 54 on the Observation window 47 (Figure 7(a)). In the preferred embodiment, the information released to the Laboratory Information System 26 via the Result Release screen 400 can include the following: (1) partial and/or final organism identifications up to a maximum of 3, for example; (2) sensitivity 20 panel results; (3) results from tests recorded on the SST screens (e.g. the Specimen Specific Tests screens 300, 320, 340 or 360 shown in Figures 6(a) to 6(d)); (4) results from tests recorded on the various Test Library windows 76 (Figure 79a)); (4) user selected canned message(s); or (5) free-text comments keyed in by the user. The system 1 allows a maximum of 2 partial and 1 final reports to be released to the Laboratory Information System 26. However, the last report released to the Information System 26 must be a final report.

Referring to Figure 10, the technician can use the Result Release screen 400 to make a partial or a final report to the patient's 30 physician. The Result Release screen 400 includes a Report type select panel 402 which comprises a "FINAL" report radio button 403 and a "PARTIAL" report radio button 405. The system 1 uses the radio

buttons 403,405 to indicate whether the current contents of the Release screen 400 constitute a final or partial report if they were released right now.

The Result Release screen 400 has the capability to release 5 test results for three separate organisms for a specimen. The organisms are defined by an "Organism 1" command button 404, an "Organism 2" command button 406 and an "Organism 3" command button 408. The technician uses the command buttons 404,406,408 to select the current organism. The system 1 requires that the organisms be worked in order, i.e. organism 1, 2, 3. However, the information from any observation slot number can be entered under "Organism 1". Therefore, the technician can prioritize the identification of organisms in order of importance.

To transfer the information recorded in an observation slot number to the Result Release screen 400, there is an Observation Slot Panel 410. The Observation Slot Panel 410 comprises an array of twelve slot command buttons 412 which correspond to the observation slot numbers in the Observation window 47 (Figure 7(a)). The caption on each command button 412 indicates which observation number it represents. The system 1 only activates those slot command buttons 412 which represent observations whose state is "USED", i.e. active. The technician transfers the information from a particular observation slot, for example slot number 1 to "Organism 3", by first clicking the organism command button 408, and then clicking slot 25 command button 414 (for observation slot number 1). In response, the system 1 transfers the information which was recorded under observation number 1 to the Organism 3. Since the system 1 automatically copies the information from the selected observation slot to the selected organism, errors in transcription of the results are eliminated.

To release the test results, i.e. identification of an organism which were observed on a specimen, the Result Release screen 400 includes a "RELEASE" command button 427 which when clicked causes the system 1 to communicate the test results to the Laboratory Information System 26.

As shown in Figure 10, each organism includes a display box 415 which displays the information which is transferred from the selected observation slot number. There is an Observation Slot Number indicator 416 which indicates the source (observation number) of the information for the organism. Each organism display box 415 includes a partial id check box 418, a final id check box 420, and a series of antibiotic sensitivity check boxes 422.

Referring to Figure 10, the Partial Id check box 418 includes a label 424 and an organism name field 426. The name field 426 will contain the name of the organism which was identified by the technician under that observation slot. The state of the of Partial Id check box 418 determines how the system 1 will process the identification of the organism. If the check box 418 is "checked", the system 1 will release the name of the organism (i.e. contents of field 426) to the Laboratory Information System 26 as a partial or preliminary identification. In the examples shown in Figure 10, "PC" means Gram-Positive Cocci, "BSC" means Group C Hemolytic Streptococci, "BRC" means Branhamella Catarrhalis, and "GNDC" means Gram Negative Diplococci.

To release a result, the technician simply clicks the "RELEASE" command button 427. If the check box 418 is blank, then the system 1 will not release a preliminary identification of the organism to the Laboratory Information System 26 when the Release command button 427 is clicked. If the result has already been released to the Laboratory Information System 26, the system 1 will display the check box 418 in "greyed out" form, and the check box 418 cannot be manipulated. If the result is pending, then the system 1 will display the check box 418 in a "hashed" format. If the check box 418 is

"Checked" or "Not Checked", clicking on the check box 418 will toggle its state between "Checked" and "Not Checked".

The Final Id check box 420 is similar to the Partial Id check box 418. The Final Id check box 420 includes a label 428 and an organism name (identification) field 430. The field 430 will contain the name of the organism which was identified by the technician under that observation slot. The state of the of Final Id check box 420 determines how the system 1 will process the identification of the organism and follows the same convention as discussed above for the Partial Id check box 418.

As shown in Figure 10, there are nineteen antibiotic sensitivity check boxes 422. The antibiotic check boxes 422 correspond to the sensitivities which were recorded in the antibiotic panel 88 in the Observation window 47 (Figure 7(a)). Each antibiotic sensitivity check box 422 includes a label 432 and a sensitivity indicator 434. The label 422 comprises a three letter mnemonic which corresponds to the name of the antibiotic. For example, "PEN" stands for penicillin as shown by reference 435. The sensitivity indicator 434 comprises a single letter, where the letter "R" signifies resistance to the associated antibiotic and the letter "S" denotes sensitivity of the organism to the antibiotic.

Referring to Figure 10, the appearance of the antibiotic check box 422 indicates the sensitivity of the organism to the corresponding antibiotic. If there is no check box 422 beside a label 432, then this indicates that the observation slot number assigned to this organism doesn't have a result for this antibiotic. For example, the label "PEN" 435 does not include a check box 422. Therefore, the drug penicillin is not to be used against this organism for this patient. If the check box 422 is checked, then the system 1 will release the antibiotic result to the Laboratory Information System 26 when the Release command button 427 is clicked by the technician. The antibiotic sensitivity is indicated by the letter "R" or "S". An "unchecked" check

box 422 indicates that the antibiotic result won't be released to the Information System 26 in response to the technician clicking the Release command button 427. If the check box 422 is displayed in a "greyed" format, this signifies that the antibiotic result has already been released to the Laboratory Information System 26. For example, the sensitivity of the organism to the antibiotic "CIP" has already been released because the check box 422 and sensitivity indicator 434 appear greyed out (reference 437). If the check box 422 is displayed in a "hashed" format, this indicates that the identification for that organism is still pending. If the display style is "Checked" or "Not Checked" clicking on the check box will toggle it's state between "Checked" and "Not Checked".

As shown in Figure 10, the Observation Slot Number panel 410 includes a "Clear" command button 415. In response to the technician clicking the "Clear" button 415, the system 1 will de-assign the currently active observation slot number (e.g. slot "number 1" 414) from the selected organism number 404,406 or 408 (e.g. "Organism 3"). The Result Release screen 400 includes an indicator 417 which denotes the selected organism, for example, "Organism 3". If any results have been released for the observation slot number, then the system 1 will not de-assign it from the current organism. The system 1 allows the technician to manipulate the "Clear" button 415 at any time.

Referring to Figure 10, the Result Release screen 400 includes an "Additional Messages" list-box 438. The list-box 438 contains a list of canned messages that can be released to the Laboratory Information System 26. The messages listed in the list-box 438 are broken into two categories: (1) messages valid for the current specimen type; and (2) messages valid for all specimen types. Any message(s) which are selected from the list-box 438 will appear at the bottom of the screen in a Messages Display field 440. The system 1 will allow the technician to manipulate (i.e. select and click) the Messages list-box 438 at any time.

The Result Release screen 400 also includes a "Freetext" command button 442. The Freetext button 442 allows the technician to enter messages other than those listed in the messages box 438. When the Freetext command button 426 is clicked, the system 1 displays a 5 Freetext screen 560 (Figure 14).

Reference is next made to Figure 14, which illustrates the Freetext screen 560. The system 1 uses the Freetext screen 560 to allow the technician to enter additional comments via keyboard 14 when releasing test results. The system 1 displays the Freetext window in a modal style when the Freetext command button 426 on the Result Release window 400 is clicked.

As shown in Figure 14, the Freetext screen 560 has a text edit box 562 and an "EXIT" command button 564. The text box 562 provides a multi-line edit field in which up to 32 kilo-bytes of comments can be entered and edited. When the Freetext screen 560 is invoked any existing comments will be displayed in the text box 562. When the "Exit" command button 564 is clicked, the system 1 closes the screen 560 and returns control to the Result Release screen 400.

Dutton 427 being clicked, the system 1 releases all selected results to the Laboratory Information System 26 and the microbiology database 28 is also updated with the new status ("released") of the selected results. The system 1 then closes the Result Release screen 400 and the Observation window 47 is re-displayed. The system 1 also clears all patient information from the Observation window 47 and returns control (i.e. the active cursor) to the accession number input box 109 (Figure 7(a)). In response to the RELEASE button 427 being clicked, the system 1 also checks the results which have been selected for release. If two previous reports have been released then this report must be final. If the report is final, then all observations whose state is "USED" must be assigned to an organism number.

The Result Release screen 400 also includes a "Cancel" command button 429. If the technician clicks the "Cancel" button 429, then the system 1 closes the Result Release screen 400 and the Observation window 47 is re-displayed. The system 1 also clears all 5 patient information from the Observation window 47 and control is returned to the accession number input box 109, but no changes are made to the microbiology database 28.

The remainder of this description will consider various administrative and house-keeping functions which are included in 10 the system 1. First, however, reference is made to Figures 11(a) to 11(g) which provide six more examples for the Test Library window 76.

Test Libraries

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Reference is first made to Figure 11(a) which shows the screen for a Gram Negative Test Library 200. The system 1 displays the Gram Negative screen 200 in the Test Library location (indicated by reference 76) on the Observation window 47 in Figure 7(a) in the following instances. The current observation being displayed on the Observation window 47 is classified as a gram negative observation according to the microbiology rules embedded in the system 1 which operate on the entry made in the Observation field 82 in the Observation window 47. Or secondly, observation information is retrieved from the microbiology database 28 includes the gram negative designation.

As shown in Figure 11(a), the Gram Test screen 200 includes a number of test panels. Each of the test panels prescribes a microbiology test which is appropriate for the gram negative testing procedure. For example, there is a test panel 204 for a "Replianalyzer" instrument, which is a known microbiology testing machine, and a 30 test panel for the "Oxidase" test procedure 210.

The "Replianalyzer" test panel 204 comprises a "YES" test radio button 206 and a "NO" test radio button 208. The technician uses

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the Replianalyzer panel 204 to record in the system 1 whether the current observation has been sent to the Replianalyzer instrument for processing. The first radio button 206 is clicked for a "YES" and the second radio button is clicked for a "NO".

The "Oxidase" test panel 210 comprises an array of three radio buttons 212,214,216. The system 1 uses the "Oxidase" panel 210 to indicate whether an Oxidase test was performed on the current observation and if so, the result of the test. The first radio button 212 is clicked for a positive ("POS") test value. The second radio button 214 is clicked for a negative ("NEG") test value, and the third radio button 216 is clicked for non-applicable ("N/A") test result.

As shown in Figure 11(a), the Gram Test Negative screen 200 includes additional test panels for other known gram test negative type tests, for example, "Motility" and "Kirby Bauer", which will be understood by one skilled in the art.

The Gram Test Negative screen 200 also includes a "Next" command button 202. The system 1 uses the "Next" button 202 to return to the specimen identifier box 70 on the Observation window 47. In response to clicking the "Next" button 202, the system 1 clears the information on the Observation window 47, closes any test library window 76, updates the microbiology database 28 with any changes made to the entries under the observation.

If the information for an observation has been released, then the system 1 will not allow the technician to manipulate the Test Library window 76, e.g. the Gram Test window 200.

Figures 11(b) through 11(g) show test libraries specific to other types of microbiology tests as will be understood by one skilled in the art. Figure 11(b) shows the screen for a Gram Positive Staph Test Library 220. Figure 11(c) shows the screen for a Gram Positive Strep Test Library 230. Figure 11(d) shows the screen for a Campylobacter Test Library 240. Figure 11(e) shows the screen for a Haemophilus Species Test Library 250. Figure 11(f) shows the test

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library screen for a Neiss Test Library 260, and Figure 11(g) shows the screen for a Pseudo Test Library 270. As discussed for the Gram Test screen 200, each of these test library screens contain test panels which are specific to the results corresponding to the particular test, as will be known to one skilled in microbiology.

For example, referring to Figure 11(c), the Gram Positive Strep Test Library screen 230 includes a list-box 232 labelled as "Strep Ser.". The system 1 uses the list-box 232 to display a list of valid results for the Strep Serology (Phadebact) test. The system 1 generates the contents of this list-box from information retrieved from the microbiology database 28.

The discussion will now consider the administrative and house-keeping functions included in the electronic worksheet system 11, with reference first being made to Figure 12 which shows a Pending Reports screen indicated generally by reference 500.

The Pending Reports Screen

The Pending Reports screen 500 provides a query tool for the technician. The Pending Reports screen 500 allows the technician to display information (in variety of ways) on the number of non-final specimens in the microbiology database 28, i.e. specimens that have not been final reported. The Pending Reports screen 500 is displayed by clicking the "Pending Report" option in the Menu screen 31 (see Figure 3).

As shown in Figure 12, the Pending Report screen 500 comprises a primary display box 502, a "Specimen Types" list-box 504, a "Select ALL" command button 506, an "Include" panel 508, a "Daycodes" panel 510, an "Options" panel 512, an "Output" panel 514, an "Exit" command button 516, and an "OK" command button 518.

Referring to Figure 12, the primary display box 502 displays the result of the query. The "Specimen Types" list-box 504 contains a list of all valid specimens types for the microbiology

database 28. One or more specimen types must be selected for the query and only specimens for the selected specimen type are used in the query. The technician clicks the "Select ALL" command button 506 to select all specimen types in the "Specimen Types" list-box.

The Include panel 508 comprises an array of 4 check boxes: "Pending", "In Progress", "1st Partial", "2nd Partial", which are used by the technician to select which specimens will be included in the query. The "Pending" check box is used to display specimens that have never been accessed from the microbiology database 28. (This 10 corresponds to the information which is displayed in the "Status:" field 123 on the patient and specimen data window 42 in Figure 7(a).) The "In Progress" check box is used to display specimens that have been viewed at least once, and results may have been entered but not released to the Laboratory Information System 26. The "1st Partial" 15 check box is used to display specimens for which one partial report has been released to the Laboratory Information System 26. The "2nd Partial" check box is used to display specimens for which two partial reports have been released to the Laboratory Information System 26. The system 1 requires that at least one check box be checked before the query can be run. All boxes are checked by default.

The "Daycodes" panel 510 comprises an array of 2 Spin Controls 511 and 513. The technician uses this panel 510 to limit the scope of specimens which will be displayed by the system 1 to those having accession numbers that fall between two specific Julian dates. The value displayed defaults to the current julian date. In response to the technician clicking the spin controls 511,513, the system 1 will increment or decrement the Julian date display depending on whether the up or down arrow is clicked.

The "Options" panel 512 comprises an array of two radio 30 buttons as shown in Figure 12. The Options panel 512 is used to determine whether the results of the query are displayed in summary or detail format. The summary format includes specimen counts only. The detail format includes specimen counts and patient information (i.e. accession number and patient name).

The Output panel 514 comprises an array of two radio buttons which specify whether the results of the query are sent to the default printer 19 (Figure 1) and/or the primary display box 502. For a detailed query which is routed to the printer, the system 1 will include two pieces of additional information: the client# and requesting physician's name.

When finished the technician clicks the "Exit" command button 516 to close the "Pending Report" screen 500 and the system 1 returns control to the Menu screen 31 (Figure 3).

If the technician clicks the OK command button 518, the system 1 will first check that the proper query parameters have been defined (e.g. at least one specimen type was selected) before doing a query and displaying (and/or printing) the results of the query. The system 1 will display a dialog box (not shown) containing an explanatory message is displayed if the proper query parameters have not been defined.

Reference is next made to Figure 19 which shows an 20 Archive Screen 630.

The Archive Screen

The Archive screen 630 allows the technician to copy or archive files (using another screen (not shown)) to a floppy diskette. The system 1 displays the Archive screen 630 in a modal style and in response to the "Archive" option being selected on the Menu Screen 31.

As shown in Figure 19, the Archive screen 630 includes a list-box 632 (to display a list of files for archive), a text box 634 (to display messages/instructions for archive a file), and an "Exit" command button 636 which is used to close the Archive screen 630.

Reference is next made to Figure 20 which shows a User Authorization screen 640 which is used in the electronic worksheet system 1.

5 The Authorize Screen

The Authorization screen 640 is used by the system administrator to manage user access to the system 1. As shown in Figure 20, the Authorization Screen 640 comprises a "User ID" drop-list-box 642, a list-box command button 643, a user "Name" box 644, a "Password" box 646, a user privileges panel 648, and four command buttons: "Add" 650, "Delete" 652, "Quit" 654 and "Cancel" 656.

As will be understood by one skilled in the art, the command buttons in conjunction with the edit boxes are used to add/delete users and grant/revoke user privileges on the system 1.

The system 1 displays the Authorization screen 640 in a modal style when the "Authorization" option is selected on the Menu screen 31.

Reference is next made to Figure 21 which shows a Delete Specimen Screen 660 which is incorporated into the system 1.

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The Delete a Specimen Screen

The "Delete A Specimen" screen 660 provides an interactive interface for the technician to delete a specimen (and the associated information) from the microbiology database 28. It is, however, a feature of the system 1 that a specimen which has been final reported cannot be deleted until it has been archived. The system 1 displays the "Delete A Specimen" screen 660 in a modal style when the technician selects the "Delete Specimen" option from the Menu screen 31 in Figure 3.

As shown in Figure 21, the "Delete a Specimen" screen 660 comprises a Specimen Identifier edit box 662, a "Patient" name

display field 664, a specimen "Status" display field 666, an "Exit" command button 668, and a "Delete" command button 670.

To delete a specimen, the technician first enters the appropriate accession or bar-code identifier in the edit box 662. The system 1 verifies that the specimen exists, isn't in use, and isn't final reported. If these checks are passed, then the system 1 displays the patient's name and the specimen's status in fields 664 and 666. In response to the technician clicking the Delete button 670, the system 1 will delete the selected specimen from the microbiology database 28. If instead the technician clicks the "Exit" button 668, the system 1 will close the screen 660 and return control to the Menu screen 31 without changing the information retrieved from the microbiology database 28.

Lastly, reference is made to Figure 22 which shows an Upload/Download Control Screen 680 according to the present invention. The Upload/Download window 680 forms the user interface for the gateway application program 17 (Figure 1) which runs on the console workstation 24. Like the system program 15, the gateway program is also written to run on a Windows (trademark) platform. The Upload/Download screen 680 and console workstation 24 provide the "gateway" between the Laboratory Information System 26 and the microbiology database 28.

The technician uses the Upload/Download screen 680 to perform the following tasks: (1) process download requests and demographic update data/information packets from the Laboratory Information System 26. These requests and packets are supplied by the Laboratory Information System 26 in the form of ASCII text files and the gateway application program 17 inserts these requests into the microbiology database 28; (2) provide the Laboratory Information System 26 with the results that were released (as discussed above for the Result Release screen 400) from the microbiology database 28. The

test results are stored results in ASCII text files which will be picked up and processed by the Laboratory Information System 26.

As shown in Figure 22, the Upload/Download screen 680 includes an "Exit" command item 682, a "Download Status" check box 684, a File Name display field 686, and a pair of Upload Status display fields: a Queued display field 688 and a Completed display field 690.

The technician uses the Exit command item 682 to shutdown the system 1. In response to the technician clicking the Exit command item 682, the system 1 initiates an orderly log out of all the workstations 10 in the system 1.

The technician uses the "Download Status" check box 684 to enable/disable the system program 17 from processing download requests from the Laboratory Information System 26.

The system 1 uses the File Name field 686 to display the download request file currently being added into the microbiology database 28 (not shown) or "NO RECORDS" if all download requests have been processed. The "Queued" field 688 displays the total number of upload transactions queued for processing since the last time the system 1 was closed. Lastly, the "Completed" field 690 displays the total number of upload transactions processed since the last time the system 1 was closed.

Although various preferred embodiments of the present invention have been described in detail, it will be appreciated by those skilled in the art, that variations may be made without departing from the spirit of the invention or the scope of the appended claims.

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WE CLAIM:

- In the method of microbiological testing and reporting of 1. a patient specimen in a medium, said specimen having a machine readable identifier, the improvement comprising: providing, in a database, patient information associated with said identifier, said patient information including patient identification information and patient age and patient sex identification information, and then selecting said specimen, reading said identifier, and displaying on a 10 screen information including said patient identification information and said patient age and sex identification information, an identification of the type of said specimen, a medium box for insertion therein by a user of the type of medium used, and an observation box for insertion therein by a user of an observation concerning said specimen.
 - The method according to claim 1 including displaying on 2. said screen a list of medium types which can be associated with each specimen, and then selecting and inserting in said medium box on said screen a selected medium from said list of medium types.
 - The method according to claim 2 including displaying on 3. said screen a list of observations and the selecting and inserting in said observation box on said screen a selected observation from said list of observations.
 - The method according to claim 2 including displaying on 4. said screen a selected medium in said medium box, providing a plurality of lists of observations, one such list associated with each medium, displaying on said screen that list of observations which is associated with the medium which is displayed, and selecting and

inserting in said observation box on said screen a selected observation from said last mentioned list of observations.

5. The method according to claim 4 including displaying on said screen a description box for insertion by a user of a description relating to a said observation, providing a list of descriptions associated with each observation, and providing means for a user to select and insert in said description box a selected description from said list of descriptions.

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- 6. The method according to claim 5 wherein said screen includes a quantifier box for insertion of a quantifier concerning said specimen, and in use inserting a said quantifier in said quantifier box.
- 7. The method according to claim 6 and including the step of providing on said screen a plurality observation slot buttons, one for each observation, and including the step of associating an observation with a selected observation slot button.
- 20 8. The method according to claim 7 and including the step of marking an observation as used, said method including providing a plurality of test libraries, one test library being associated with each observation, and of displaying on said screen when said observation has been marked as used the test library associated with such observation.
 - 9. The method according to claim 7 and including the step of marking an observation as frozen, and of providing a record of said observation for audit purposes.

- 10. The method according to claim 4 wherein in each said list of observations, the individual observations are listed in most likely order of appearance, with the most likely observation appearing first.
- 5 11. The method according to claim 1 wherein said patient identification information, said patient age and sex identification information, and said identification of the type of said specimen are displayed at the top of said screen.
- 10 12. The method according to claim 7 including the step of associating information concerning a medium, observation, description and quantifier with a first observation slot button, and then recording on said screen information concerning a second medium, observation, description and quantifier and associating such information with a second observation slot button.
- 13. The method according to any of claims 1 to 7 and including the step of selecting an additional specimen container carrying a second machine readable identifier, reading said identifier, associating said second machine readable identifier with said first mentioned identifier, and placing a portion of said specimen on said second container.
- 14. The method according to claim 8 and including the step,
 25 after marking a said observation as used, of selecting an additional
 specimen container carrying a second machine readable identifier,
 associating said second machine readable identifier with said first
 mentioned identifier and with said observation which has been
 marked as used, placing a portion of said specimen on said second
 30 container, sub-culturing said portion to produce a subculture,
 assigning an observation including a medium type, observation and
 description to said subculture, displaying on said screen a set of

subculture slot buttons, said set being associated with the slot button of said observation which has been marked as used, and assigning said observation of said subculture to one of said subculture slot buttons.

- 5 15. The method according to claim 7 and including the step, after inserting said quantifier in said quantifier box, of displaying a menu containing items for designating an observation as used, frozen or informational, and then selecting one of said menu items, the used item indicating that analysis using the observation entered in said observation box is to be continued, the frozen item causing the observation entered in said observation box to be frozen and hence unchangeable but providing a record thereof for audit purposes, and said informational item indicating that the entry in said observation box is for information only but that analysis thereof will be discontinued.
 - 16. The method according to claim 7 and including providing a list of drug types and drug sensitivities which are associated with each combination of medium and observation which may be entered, and providing means for a user to select and display on said screen one of the drug sensitivities from said list.
- 17. The method according to claim 16 wherein said drug sensitivities include a drug sensitive indicator, a drug resistant
 25 indicator and a do not report sensitivity indicator, and in use displaying on said screen one of said drug sensitivities.
- 18. The method according to claim 3 including displaying a box on said screen for insertion of a partial identification of an observation concerning said specimen, and in use inserting a partial identification in said box for subsequent verification of said observation.

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19. The method according to claim 3 including displaying a box on said screen for insertion of a final identification concerning said specimen, and in use inserting therein a final identification of an observation for reporting.

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20. The method according to claim 19 and including providing a pending report screen, said pending report screen having means for displaying a plurality of specimens which do not have a final identification.

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- 21. The method according to claim 1 and including providing a release screen, said release screen displaying entries for a plurality of organisms, said release screen also displaying said slot buttons, said release screen containing a box associated with each organism to enter observation information associated with a selected slot button.
- The method according to claim 20 and including the step of highlighting, in the display of slot buttons on said release screen,
 those slot buttons which have observation information associated therewith.
- The method according to claim 21 and including the step of releasing information from said release screen to a central computer, but preventing such release until all information associated with each slot button has been used or designated as not to be used.
- 24. The method according to claim 1 and including providing means for displaying a plurality of specimen specific screens 30 for each associated with a different type of specimen, and providing in each specimen specific screen an identification of the type of specimen with which such screen is associated, and a box for insertion of a

default report in the event that no abnormality is detected for such specimen, and further providing in each specimen screen a list of possible observations to be inserted specific to the specimen with which such screen is associated.

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25. The method according to claim 3 including providing on said screen a box for insertion of a final identification concerning said specimen, and in use inserting a final identification of an observation for reporting.

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26. The method according to claim 1 wherein said patient information associated with said identifier includes note information, in use said note information being displayed on said screen for the user.

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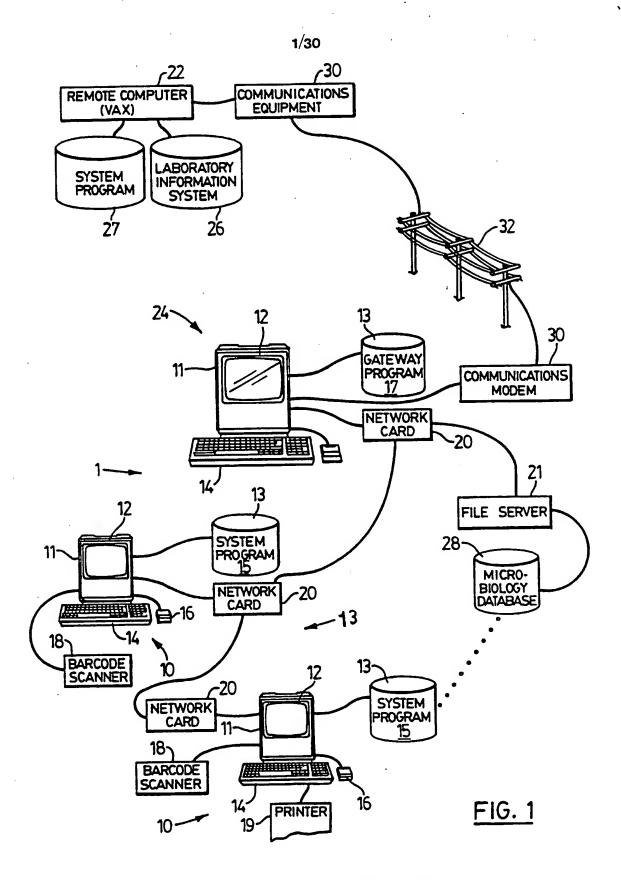
27. The method according to claim 18 wherein said patient information associated with said identifier includes note information, said note information directing the user to enter a partial identification for reporting of said patient specimen.

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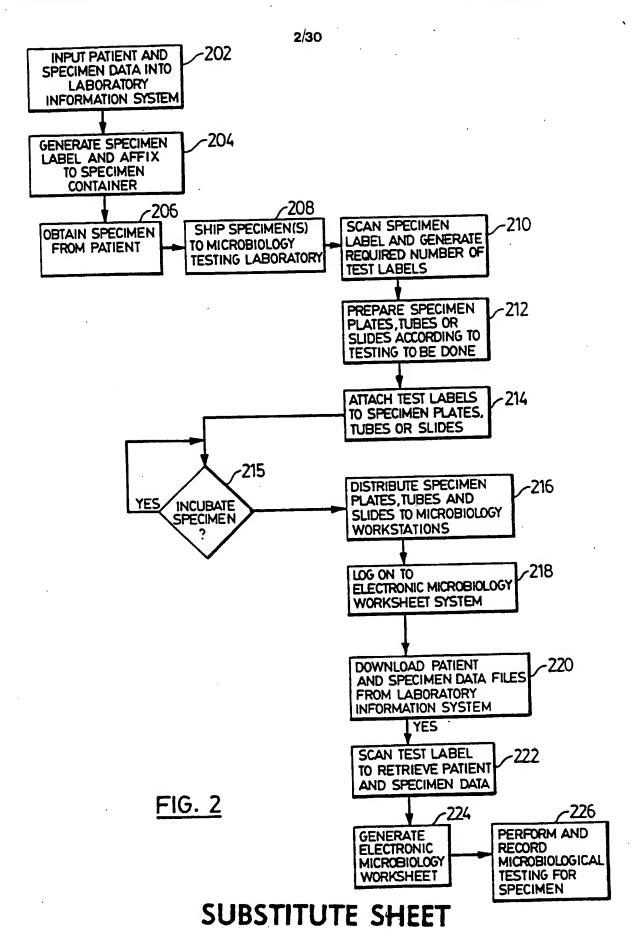
28. In the method of microbiological testing and reporting of a patient specimen in a medium, said specimen having a machine readable identifier, the improvement comprising: providing, in a database, patient information associated with said identifier, said patient information including patient identification information and patient age and patient sex identification information, and then selecting said specimen, reading said identifier, and displaying on a screen information including said patient identification information and said patient age and sex identification information, an identification of the type of said specimen, a list of possible observations to be inserted specific to such specimen, and a box for

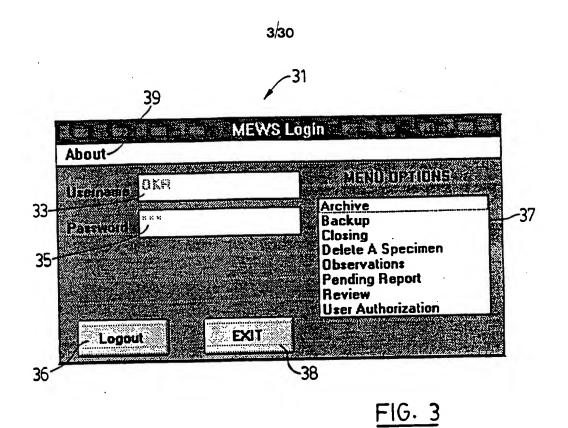
insertion of a default report in the event that no abnormality is detected for said specimen.

29. The method according to claim 28 and including the step, if an abnormality is detected in said specimen, of exiting said screen and then displaying a generic observation screen, said generic observation screen also displaying thereon said patient identification information, said patient age and sex identification information, and identification of the type of said specimen, said generic observation screen further displaying a medium box for insertion therein by a user of the type of medium used, and an observation box for insertion therein by a user of an observation concerning said specimen.

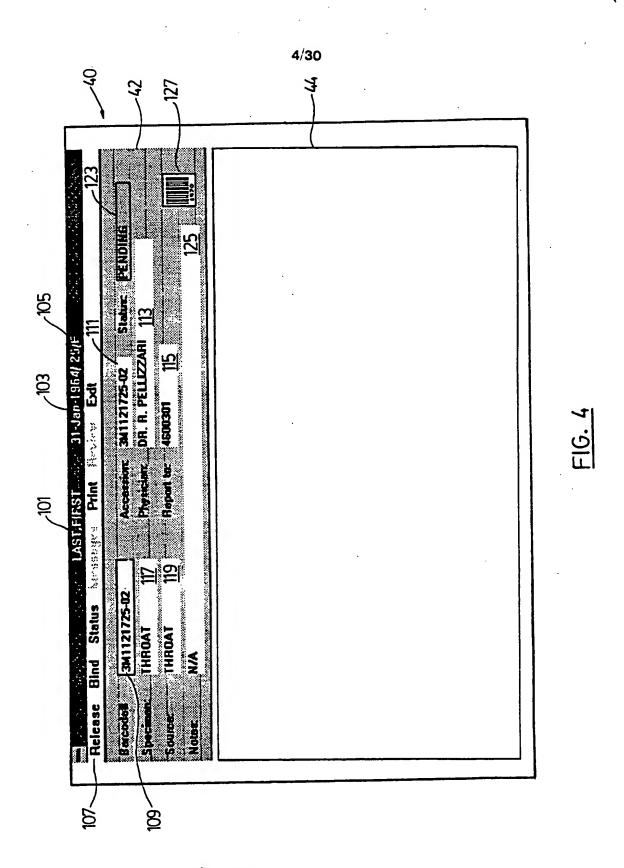


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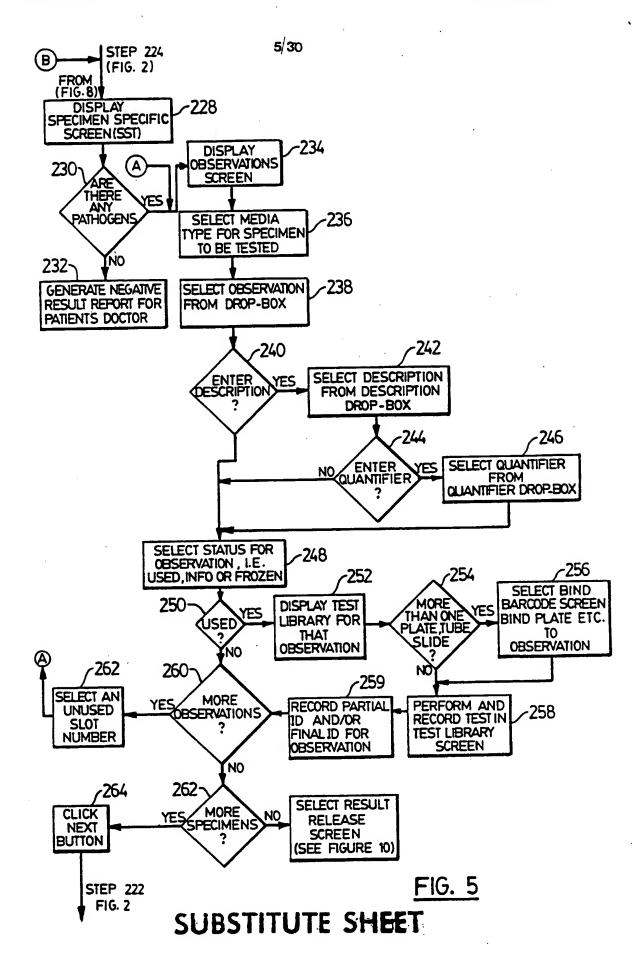


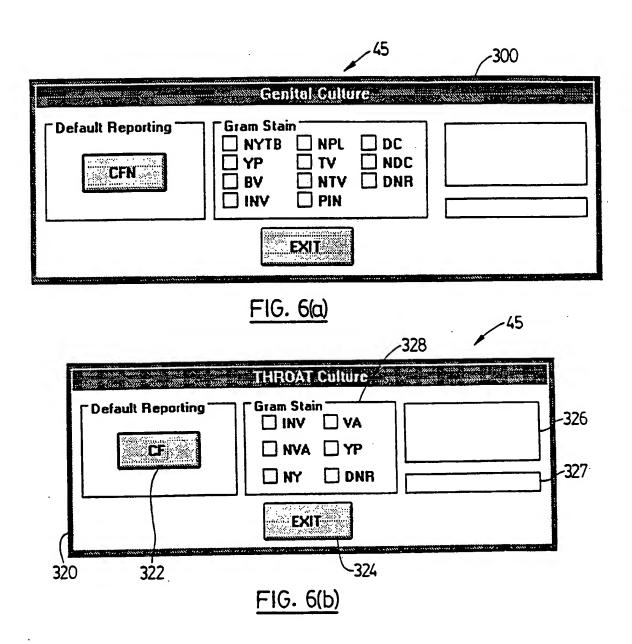


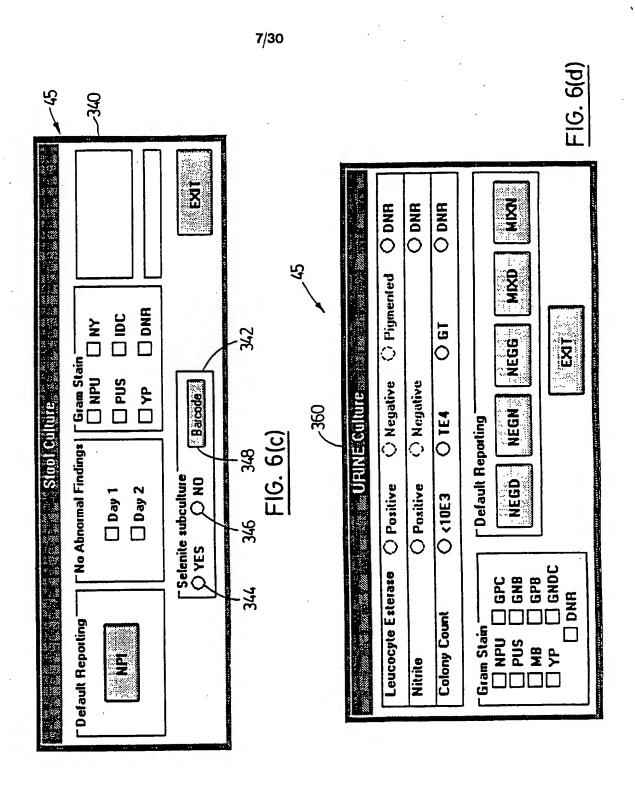
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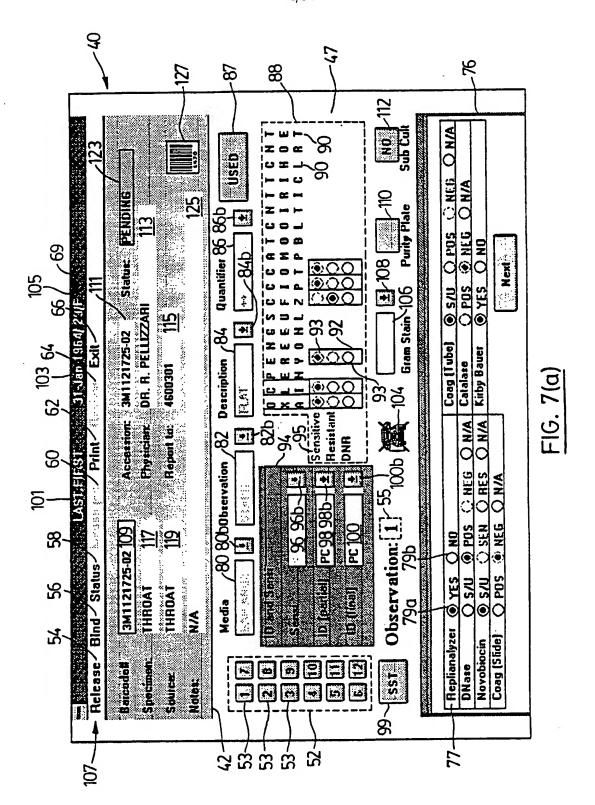






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370	Default Reporting	FIG. 6(e)



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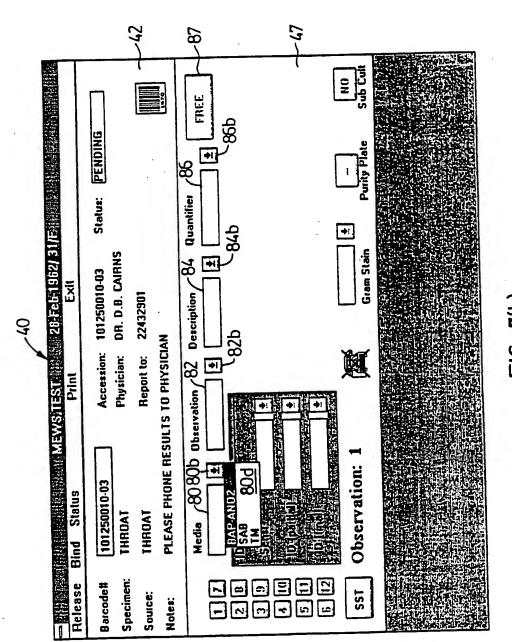
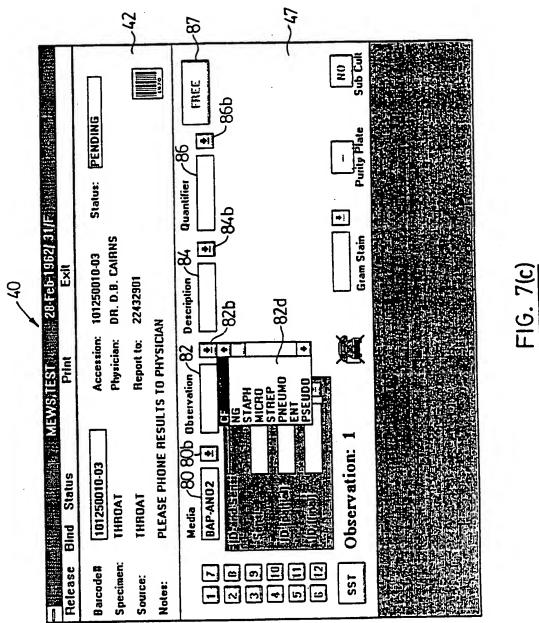
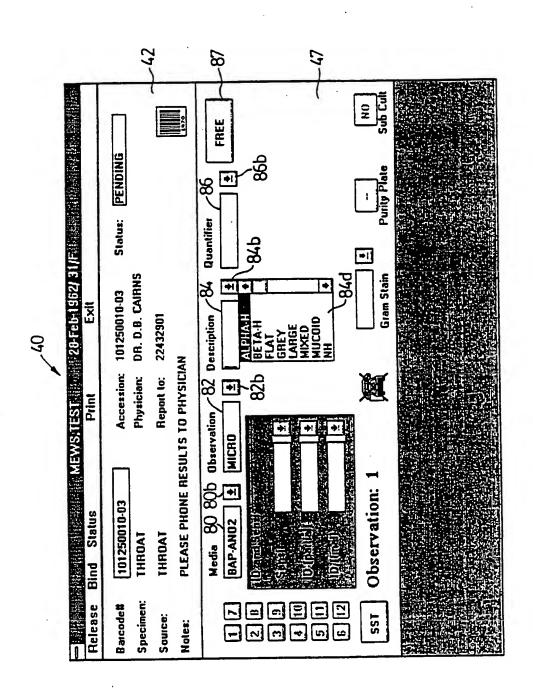


FIG. 7(b)



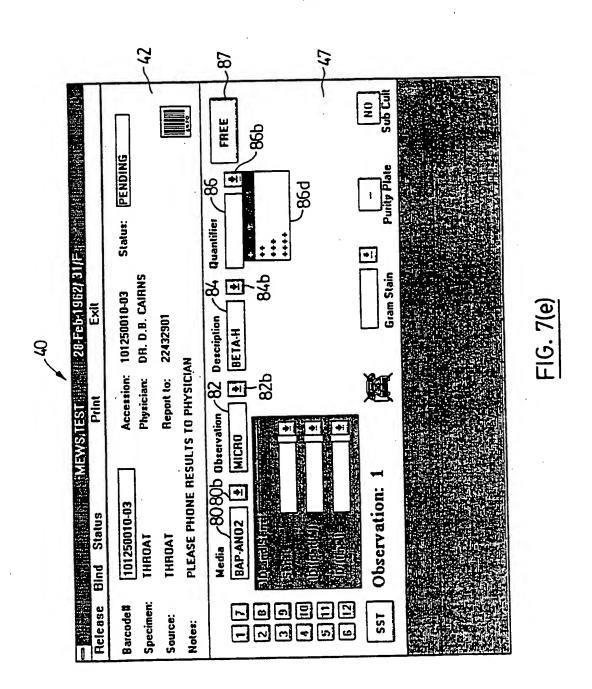
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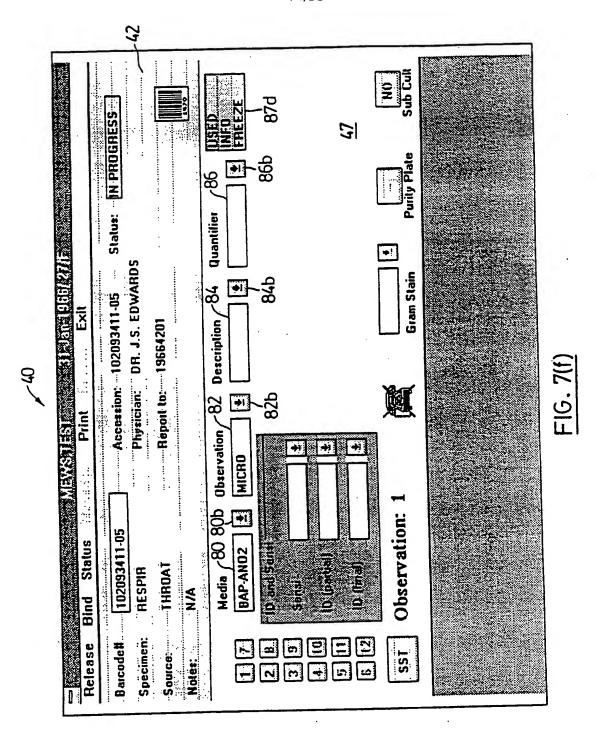


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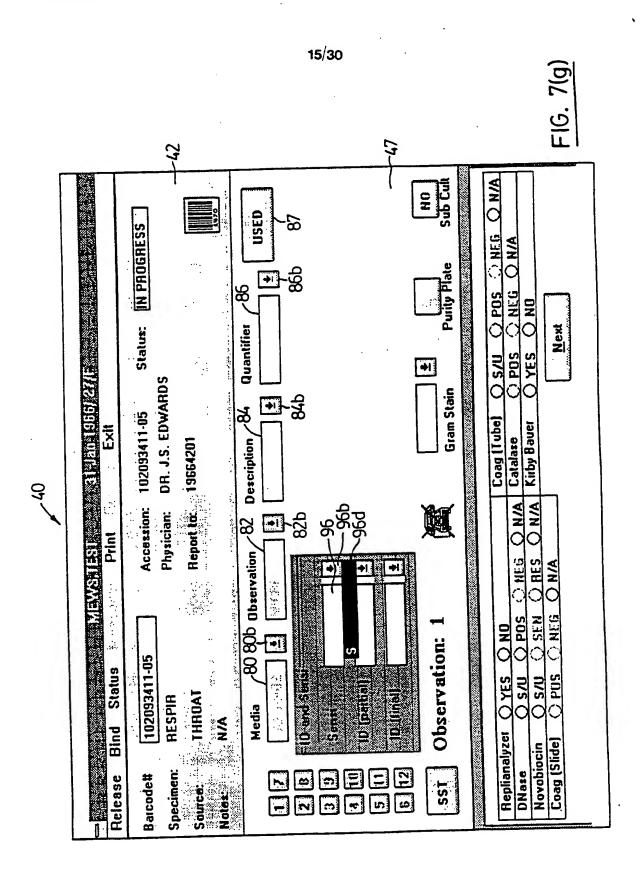
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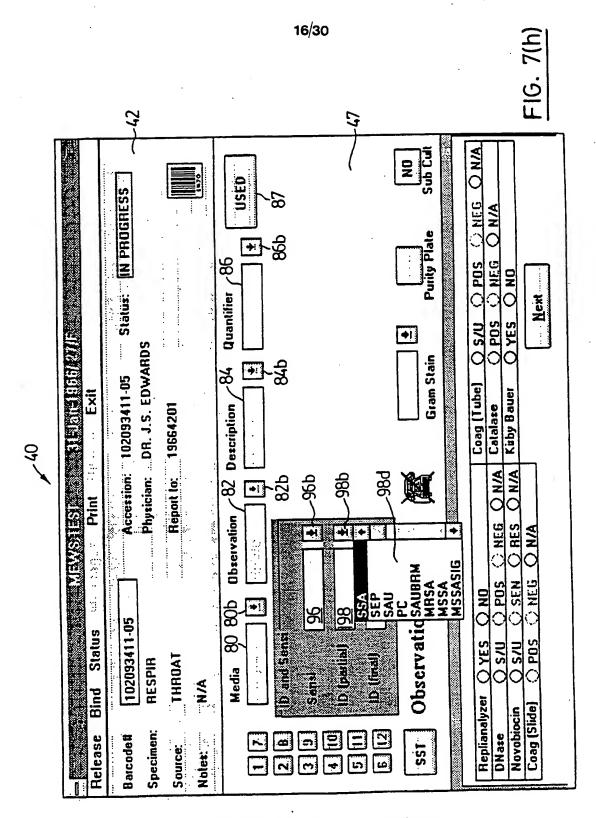
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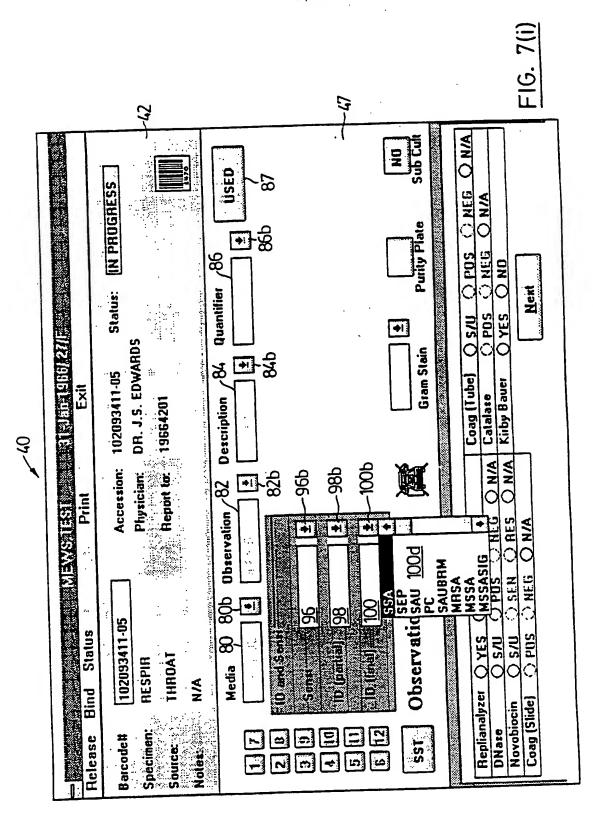
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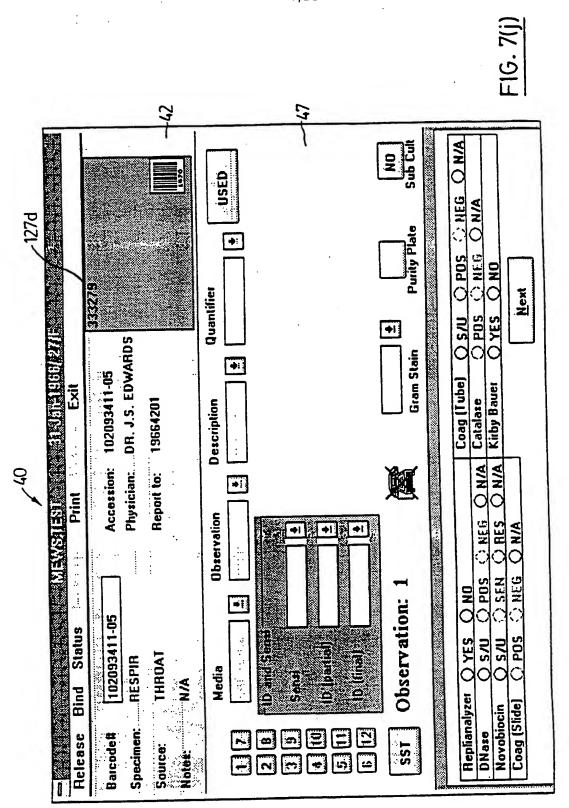
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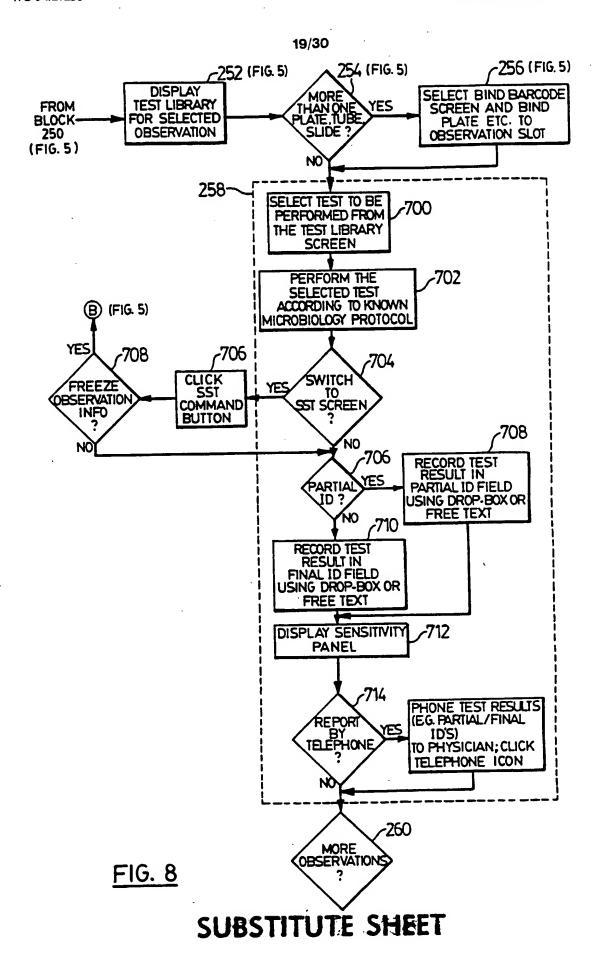


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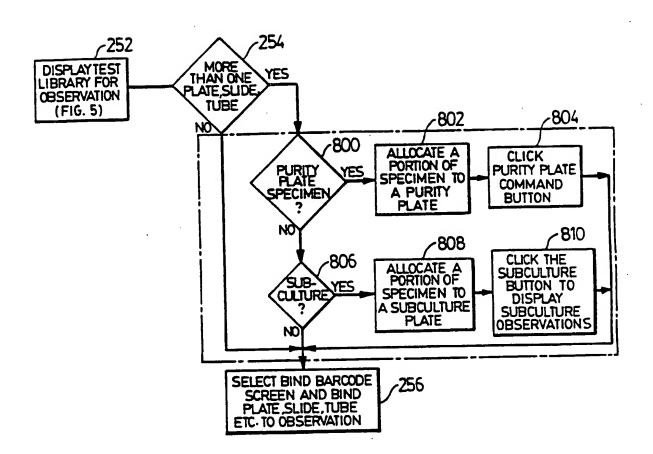
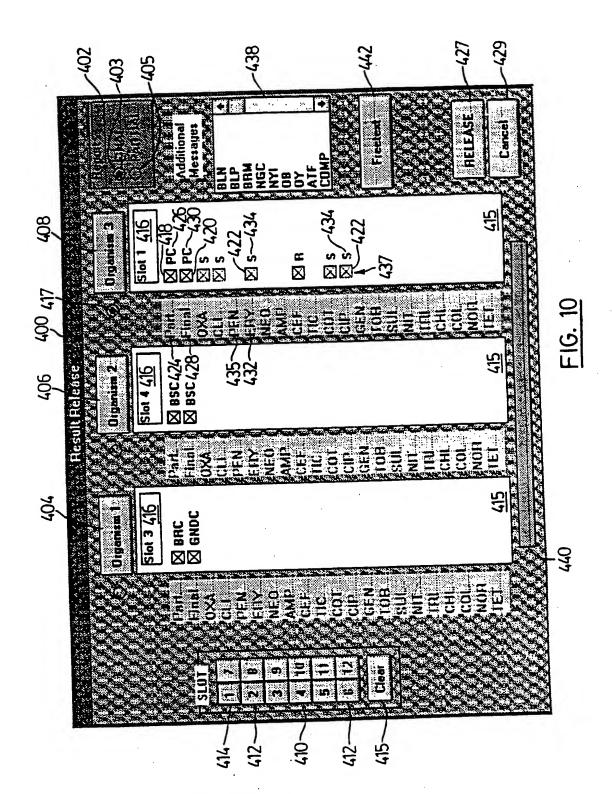
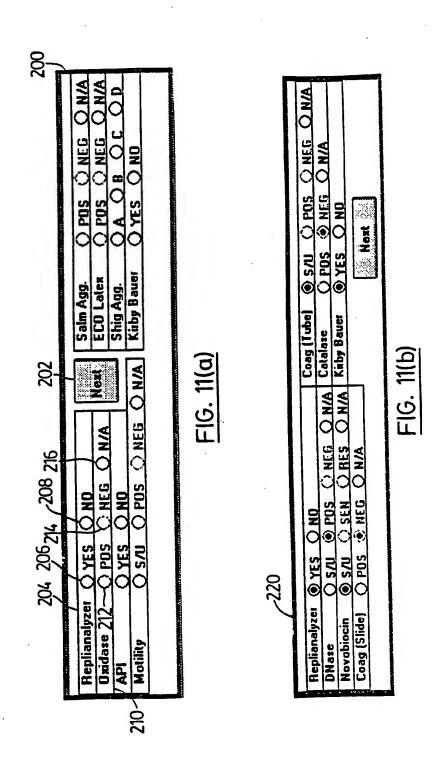


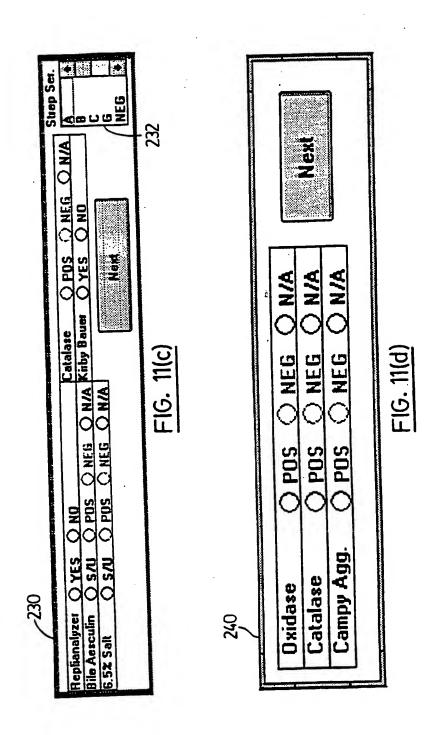
FIG. 9



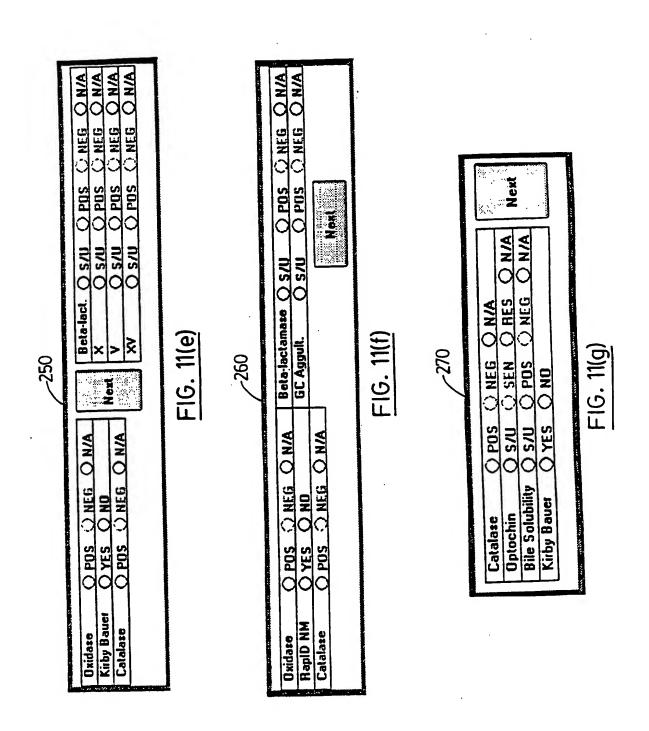
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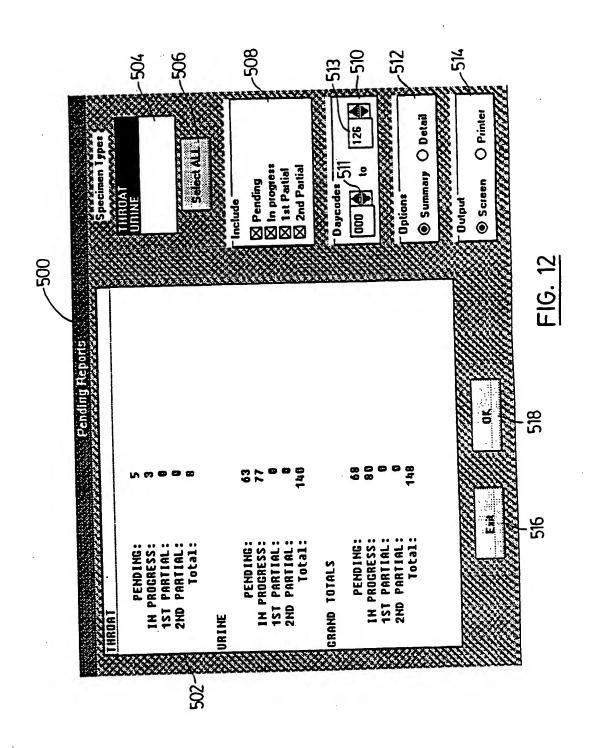


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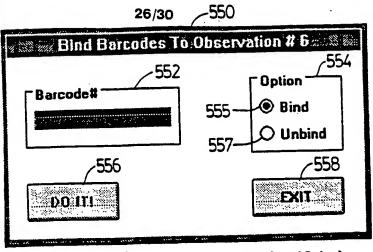
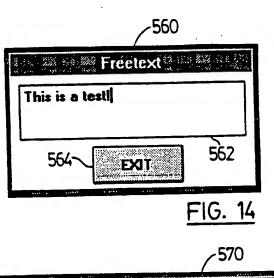


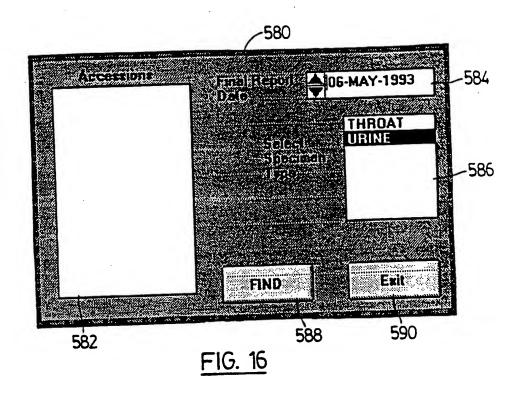
FIG. 13(a)

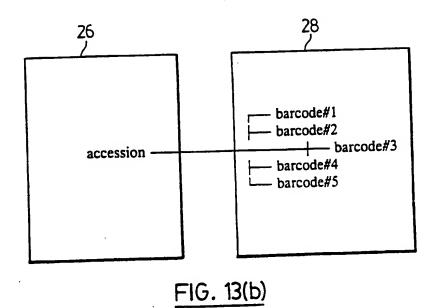


	ned & Freetext FPORT (User: 0		
Canned Messag Freetext This is a test!	ges: MOH		
	Exit	572 ⁵	

FIG. 15

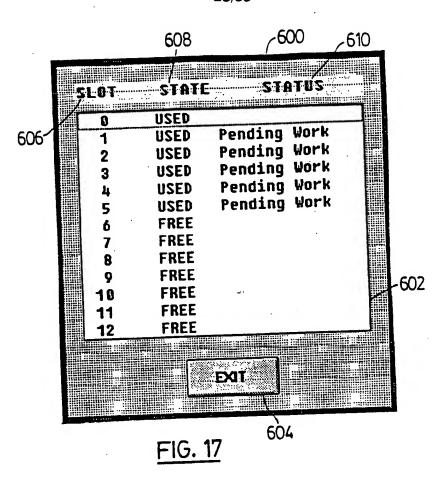
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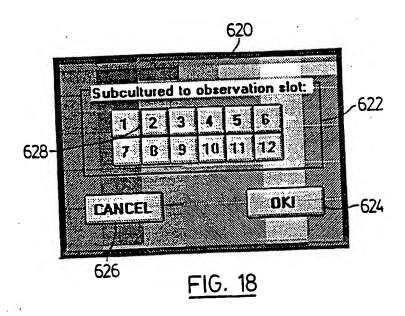




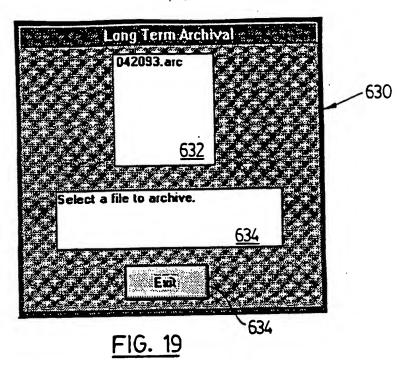
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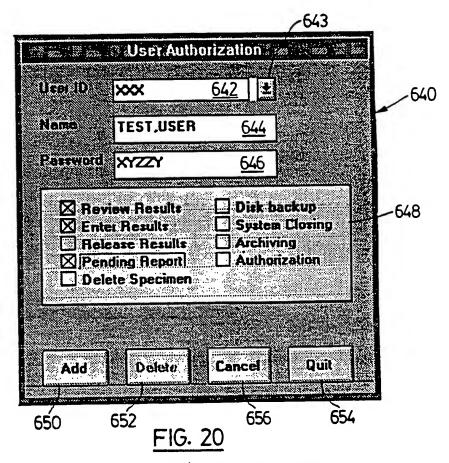




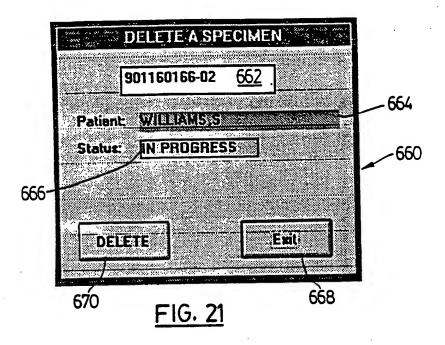


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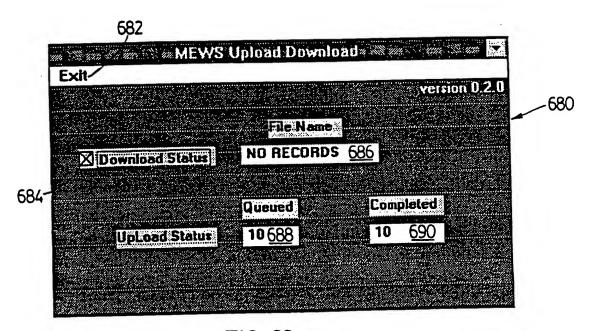


FIG. 22
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INTERNATIONAL SEARCH REPORT

nal Application No

PCT/CA 94/00216 A. CLASSIFICATION OF SUBJECT MATTER IPC 5 G06F15/42 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 5 G06F Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Y US,A,5 077 666 (J.E. BRIMM) 31 December 1-29 1991 see column 4, line 18 - line 50 see column 6, line 33 - line 63 see column 7, line 50 - column 8, line 65 see column 9, line 1 - line 7 see column 9, line 39 - line 534 1-29 P,Y US,A,5 247 611 (R. NORDEN-PAUL ET AL) 21 September 1993 see column 4, line 27 - line 37 see column 6, line 33 - line 68 1-29 FR,A,2 607 286 (MARIOTTI J.A., FR) 27 May A see page 2, line 13 - page 4, line 2 Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the *A* document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-"O" document referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled in the art. other means document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 15.09.94 2 September 1994

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Authorized officer

Barba, M

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/CA 94/00216

		PC1/CA 94/00210	
C.(Continua	nion) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
A	CHEMOMETRICS AND INTELIGENT LABORATORY SYSTEMS: LABORATORY INFORMATION MANAGEMENT, ELSEVIER SCIENCE PUBLISHERS B.V., vol.17, no.2, November 1992, AMSTERDAM NL pages 187 - 191, XP000321920 M.PRADELLA ET AL 'IMMUNOASSAY DATA MANAGEMENT AND LIMS: A PC-BASED SYSTEM IN A CLINICAL LABORATORY' see page 189, left column, line 9 - page 190, right column, line 2	1-29	
A	AMERICAN JOURNAL OF CLINICAL PATHOLOGY, vol.67, no.1, January 1977, US pages 64 - 76 B.DREWINKO 'COMPUTERIZED HEMATOLOGY: OPERATION OF A HIGH-VOLUME HEMATOLOGY LABORATORY' see page 68, left column, line 10 - page 70, right column, line 3 see page 73, right column, line 1 - page 74, right column, line 17	1-29	
	ANNALS OF CHEMICAL BIOCHEMISTRY, vol.15, no.5, September 1978, UK pages 276 - 280 P.A.JOMAIN ET AL 'DEALING WITH SPECIMEN PROBLEMS IN A COMPUTERISED CLINICAL CHEMISTRY LABORATORY' see page 276, right column, line 13 - page 277, left column, line 22 see page 278, left column, line 14 - line 36	1-29	
A	JOURNAL OF CLINICAL PATHOLOGY, vol.36, no.8, August 1983, UK pages 847 - 855 D.NEUMEIER ET AL 'A DATA PROCESSING SYSTEM DAPTED TO THE SPECIAL NEEDS OF THE EMERCENCY LABORATORY' see page 847, right column, line 17 - page 849, left column, line 24	1-29	
A	PROCEEDINGS OF THE EIGHTH ANNUAL SYMPOSIUM ON COMPUTER APPLICATIONS IN MEDICAL CARE, IEEE COMPUTER SOCIETY PRESS, US, 4 November 1984, WASHINGTON DC US pages 253 - 256 R.E.DAYHOFF ET AL 'NEWBORN SCREENING INFORMATION SYSTEM (NBSIS)' see page 253, left column, line 38 - page 255, right column, line 40	1-29	

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INTERNATIONAL SEARCH REPORT

... formation on patent family members

Inten al Application No PCT/CA 94/00216

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5077666	31-12-91	NONE	
US-A-5247611	21-09-93	NONE	
FR-A-2607286	27-05-88	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)